IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

CARLOS PÉREZ-COTAPOS UGARTE, MARIA ISABEL URETA BAZÁN, CARLOS PÉREZ-COTAPOS SUBERCASEAUX, INVERSIONES ANE MIREN LIMITADA, SHERYL GROVE, and HOORIEH ALAGHEMAND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

CASSAVA SCIENCES, INC., RICHARD JON BARRY, JAMES W. KUPIEC, REMI BARBIER, LINDSAY BURNS, and ERIC SCHOEN,

Defendants.

Case No. 1:24-CV-01525-DAE

DEFENDANTS CASSAVA SCIENCES INC.'S, RICHARD JON BARRY'S, JAMES W. KUPIEC'S, AND ERIC SCHOEN'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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Cases

This action is the latest in a string of overlapping securities class actions filed against these Defendants. All the others have been consolidated. Plaintiffs' Amended Complaint, Dkt. 49 ("Am. Compl."), is the third attempt by their counsel to take the mantle of lead counsel for this case and once again piggybacks on claims that have been pending and actively litigated for years in *In re Cassava Sciences, Inc. Securities Litigation*, No. 1:21-cv-751-DAE (the "Consolidated Action").[1]

The Amended Complaint reprises the same alleged scheme against the same Defendants and turns on the same core questions: the integrity of pre-clinical and clinical data concerning Cassava's Alzheimer's drug candidate, simufilam; the purported misconduct of Cassava's collaborator, Dr. Hoau-Yan Wang; an alleged effort by Defendants to cover up those issues following public criticism; and the supposed import of the same 2024 "corrective disclosures." The Amended Complaint's only claimed distinction is temporal. It begins the proposed class period one day after the Consolidated Action's class period ends, then points to a handful of subsequent statements—about investigations, Phase 2 data, and executive departures—as purported efforts to continue to perpetuate the same alleged deception.

Counsel's attempt to manufacture a distinct case to justify lead counsel status is flawed. To the extent it purports to offer anything new, the pleading fails to state a claim. It does not allege particularized facts showing that any challenged statement made during the alleged class period was false when made, that any Defendant acted with scienter, or that any purported corrective disclosure caused investors' losses. To the contrary, the targeted statements were accurate, and none of Plaintiffs' alleged "corrective" disclosures demonstrate otherwise.

[1] Defendants have filed Motions to Consolidate this action into the Consolidated Action, which, if granted, could obviate the need to decide this Motion to Dismiss. *See* Dkt. 53; Consolidated Action, Dkt. 338.

The Amended Complaint should be dismissed with prejudice if it is not consolidated into the existing Consolidated Action.

BACKGROUND

A. Factual Allegations in the Amended Complaint[2]

Cassava Sciences, Inc. ("Cassava") is a biotechnology company based in Austin. During the Proposed Class Period (October 13, 2023, through March 25, 2025), Cassava's only therapeutic candidate was simufilam, an investigational treatment for Alzheimer's disease. Am. Compl. ¶¶ 1–2. Between 2012 and 2021, Cassava completed pre-clinical research, a Phase 1 study, and two Phase 2 clinical studies of simufilam with the help of outside collaborator Dr. Hoau-Yan Wang of the City University of New York ("CUNY"). *See id.* ¶¶ 3–6. Cassava also began a longer 24-month open-label Phase 2 study. *Id.* ¶ 3.

Beginning in August 2021, Cassava became embroiled in public controversy concerning alleged research misconduct and data manipulation related to its pre-clinical and clinical work on simufilam. *Id.* ¶¶ 4–5. Specifically, a Citizen Petition filed with the FDA challenged the integrity of pre-clinical publications about simufilam's mechanism of action and questioned the Phase 2b results. *Id.* ¶¶ 5, 67–69. Following the Citizen Petition, the SEC, DOJ, and CUNY began investigating the allegations. *Id.* ¶¶ 73–76, 79–81.

While these investigations ran their course, Cassava moved forward with planning and executing two Phase 3 trials—RETHINK-ALZ and REFOCUS-ALZ—which were designed to test the safety and efficacy of simufilam in more than 1,900 patients with mild-to-moderate Alzheimer's disease. *Id.* ¶¶ 92–98. The trials tested the effect of 50-mg and 100-mg doses of simufilam versus a placebo over 52- and 76-week periods. *Id.* The trials occurred at clinical sites

[2] By repeating Plaintiffs' allegations from the Amended Complaint, Defendants do not adopt those allegations or in any way concede their truth.

in the U.S., Canada, Australia, Puerto Rico, and South Korea. *Id.* Between April and September 2022, before beginning the trials, Cassava audited and inspected Dr. Wang's CUNY laboratory and concluded that the lab was "temporarily not qualified" for future Cassava work. *Id.* ¶ 78.[3]

On October 12, 2023, *Science* magazine published a leaked, approximately 50-page draft document that purported to report results of CUNY's internal inquiry into allegations of research misconduct by Dr. Wang (the "CUNY Report"). *Id.* ¶ 79. The report said that the committee was "unable to objectively assess the merits of the allegations" because Dr. Wang failed to produce underlying data and records and because the available published images were of low quality. *Id.*[4]

The same day, Cassava issued a statement explaining that: (1) CUNY did not interview any Cassava employees; (2) the CUNY Report made "no findings of data manipulation" and only definitively found issues with Dr. Wang's internal recordkeeping; and (3) doubts existed about the authenticity of the report. *Id.* ¶¶ 80, 123. Later that month, CUNY stated it would not comment on the accuracy of the investigation referenced in the media because no final action had been taken. *Id.* ¶ 81. CUNY also recognized questions about the "confidentiality and integrity" of the process and thus stayed the underlying investigation pending a comprehensive review. *Id.*

By November 2023, Cassava had completed its 24-month open-label Phase 2 study, and its Phase 3 trials had been fully enrolled. *Id.* ¶¶ 63, 98, 112–115. On February 7, 2024, Cassava announced top-line results from the open-label study. *Id.* ¶ 159. The Company stated that 47 mild

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[3] The Court can find this audit report attached to this Motion as Exhibit A. The Court may consider documents attached to a motion to dismiss if the documents are "sufficiently referenced in the complaint." *Walch v. Adjutant Gen.'s Dep't of Texas*, 533 F.3d 289, 294 (5th Cir. 2008).

[4] The CUNY Report is only available for download through the October 12, 2023, *Science* article referenced above. However, the document is password-protected and cannot be filed with the Court using the ECF filing system. The document can be found at the following URL: https://www.science.org/do/10.1126/science.adl3444/full/cuny_wang_final_report-1698701360173.pdf. *See Walch*, 533 F.3d at 294.

Alzheimer's patients receiving continuous simufilam for 24 months had no decline in ADAS-Cog (a measure of cognition) as a group, while 40 non-continuous mild patients declined only 1 point as a group. *Id.* ¶¶ 99, 160. For moderate Alzheimer's, 32 continuously treated patients declined 11.05 points on ADAS-Cog as a group. *Id.* ¶¶ 159–163.[5] Cassava repeated this summary in its 2023 Annual Report and Q1–Q3 2024 Forms 10-Q. *Id.* ¶¶ 162–164.

In late February 2024, Cassava disclosed that an internal investigation conducted by outside counsel had "found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct." *Id.* ¶¶ 129–30. The Company also stated then (as well as on multiple other occasions between November 2023 and May 2024) that no government agency had informed Cassava that it found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors. *Id.* ¶¶ 125, 127.

In the summer of 2024, the status of the government's investigations changed. On June 28, 2024, DOJ indicted Dr. Wang for allegedly manipulating western blot images in pre-clinical research submitted to the National Institutes of Health (NIH). *Id.* ¶¶ 86, 137. DOJ did not bring any charges against Cassava or any of the Company's current or former employees. On October 23, 2025, DOJ voluntarily dismissed the case against Dr. Wang with prejudice after a jury had been chosen.[6]

On July 1, 2024, Cassava filed an 8-K disclosing that the SEC had told the Company that Dr. Wang could theoretically have used statistics in a May 14, 2020 email attachment sent from

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[5] The Court can find the February 7, 2024 press release announcing these results attached to this Motion as Exhibit B. *See id.*

[6] The Court can find the order of dismissal attached to this Motion as Exhibit C. *See Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("it is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.").

Dr. Burns to Dr. Wang to unblind himself as to some Phase 2b participants. *Id.* ¶¶ 141, 148. On July 17, 2024, Mr. Barbier and Dr. Burns resigned from Cassava "other than for cause," and Rick Barry was appointed Executive Chairman and principal executive officer (later CEO). *Id.* ¶¶ 144–147. On August 8, 2024, Cassava cautioned investors not to place undue reliance on the CUNY CSF (cerebrospinal fluid) bioanalysis underlying the Phase 2b results and disclosed that it was in "advanced" settlement discussions with the SEC. *Id.* ¶¶ 149, 151.

On September 26, 2024, the SEC filed a civil complaint against Cassava, Mr. Barbier, and Dr. Burns concerning statements about the 2020 Phase 2b results, and Cassava announced that it had settled with SEC. *Id.* ¶¶ 153–55. Cassava, without admitting or denying the SEC's allegations, agreed to pay a monetary penalty of $40 million. *Id.* The SEC's charges included only negligent disclosure failures. It did not bring any fraud charges against Cassava, Mr. Barbier, or Dr. Burns or otherwise allege that Cassava or any current or former Cassava employees committed fraud. And while the SEC separately charged Dr. Wang with manipulating or fabricating simufilam's Phase 2b research results, *see id.* ¶ 156, the SEC did not allege that Cassava, Mr. Barbier, or Dr. Burns had intentionally or knowingly aided Dr. Wang in doing so.[7]

On November 25, 2024, Cassava announced that RETHINK-ALZ failed to meet its clinical endpoints. *Id.* ¶ 178. Cassava discontinued REFOCUS-ALZ and the Phase 3 open-label extension. *Id.* ¶ 119. On March 25, 2025, top-line data showed REFOCUS-ALZ likewise failed to meet its endpoints. *Id.* ¶ 186. Cassava therefore announced it would discontinue efforts to develop simufilam for Alzheimer's disease. *Id.* ¶¶ 187–190.

B. Procedural Background

1. *The Consolidated Action*

[7] The Court can find the SEC Complaint attached to this Motion as Exhibit D. *See Norris*, 500 F.3d at 461 n.9; *Walch*, 533 F.3d at 294.

In August 2021, after the Citizen Petition was made public, several putative securities class actions were filed in this District against Cassava and certain officers. On June 30, 2022, this Court consolidated those actions as *In re Cassava Sciences, Inc. Securities Litigation*, appointed a lead plaintiff, and approved lead counsel. *See* Consolidated Action, Dkt. 59. The same counsel representing Plaintiffs in the instant action, Pomerantz LLP, filed a motion for appointment as lead plaintiff and approval of counsel, which this Court denied. *See id.*, Dkt. 38, 59. The lead plaintiff in the Consolidated Action filed an operative pleading in August 2022 defining a class period of September 14, 2020, to July 26, 2022. *See id.,* Dkt. 68, ¶ 46. The consolidation order in the Consolidated Action provides that "any other actions now pending or hereafter filed in this District that *arise out of the same facts and claims* as alleged in the [consolidated] actions *shall be consolidated* into the Consolidated Action for all purposes once the Court is informed of them." *See id.*, Dkt. 58, ¶ 5 (emphasis added).

After failing to secure lead counsel status in the Consolidated Action, Pomerantz LLP tried another approach. In February 2024, the firm filed a separate, overlapping case in the Northern District of Illinois—*Baker v. Cassava Sciences, Inc.*, No. 1:24-cv-977 (the "Baker Action"), which began its class period the day after the end of the class period in the then-operative complaint in the Consolidated Action. *See* Baker Action, Dkt. 1. The Consolidated Action plaintiffs moved to transfer and consolidate the Baker Action, explaining that it was a continuation of the same scheme they had already alleged. *See id.*, Dkt. 12. On May 28, 2024, the Baker Action was transferred to the Western District of Texas, *see id.*, Dkt. 42. This Court then consolidated *Baker* pursuant to the June 2022 order. *See* No. 1:24-cv-590-DAE, Dkt. 73. Thereafter, the plaintiffs in the Consolidated Action obtained leave to supplement their complaint and added several 2024 developments, including the June 2024 indictment of Dr. Hoau-Yan Wang, the July 2024 leadership changes, and

the September 2024 SEC resolution. *See* Consolidated Action, Dkts. 175, 176. And on May 22, 2025, lead plaintiffs filed a Second Supplemented Consolidated Complaint, now the operative pleading in the Consolidated Action. *See id.*, Dkt. 319.

The operative complaint in the Consolidated Action broadly alleges that between September 14, 2020, and October 12, 2023, Cassava Sciences and several executives, including Mr. Barbier, Dr. Burns, and Mr. Schoen, misled investors about the scientific validity of simufilam. *See id.* ¶¶ 1–3, 46, 69–72, 287. The complaint asserts that Cassava's foundational pre-clinical and clinical studies were manipulated and contained falsified data produced by Dr. Wang and Dr. Burns. *See id.* ¶¶ 146–148, 216, 287. The complaint further alleges that, following the 2021 Citizen Petition, Cassava falsely denied wrongdoing, issued public statements that were allegedly knowingly false about the status of government investigations, and submitted doctored images to journals to obtain exculpatory notices. *See id.* ¶¶ 319–321, 331–336, 338–345, 363–367, 386–391, 451–453. The complaint concludes that Defendants' manipulation of data and concealment of their wrongdoing was revealed by, among other things, the leak of the October 2023 CUNY Report; the June 28, 2024 DOJ indictment of Dr. Wang for major fraud; the Company's 8-K filings and press releases in July and August of 2024; and the September 26, 2024 SEC charges against Cassava, Mr. Barbier, and Dr. Burns. *See id.* ¶¶ 1–5, 506.

2. *The Instant Action*

Filed in December 2024, the original complaint (then captioned *Crocker v. Cassava Sciences, Inc.)* focused narrowly on Cassava's Phase 3 clinical trial results and proposed a February 7 to November 24, 2024 class period. *See* Dkt. 1. After the lead-plaintiff process concluded, newly appointed lead plaintiffs—represented again by Pomerantz LLP—filed the operative Amended Complaint in August, *see* Dkt. 49, abandoning the original, narrow focus on Phase 3. Like the Baker Action before it, the Amended Complaint copied the same multi-year

scheme alleged in the Consolidated Action and proposed a class period that runs from the day after the end of the Consolidated Action's current class period (October 13, 2023) through March 25, 2025. The Amended Complaint also added individual defendants from the Consolidated Action: Remi Barbier, Eric Schoen, and Dr. Lindsay Burns.

Adopting the narrative in the Consolidated Action, Pomerantz's Plaintiffs now allege that Cassava and certain current and former executives continued to mislead investors through an ongoing cover-up of the same supposed fraud alleged in the Consolidated Complaint. Specifically, Plaintiffs allege that Defendants falsely: (1) misrepresented the outcome and status of government, internal, and third-party investigations, *see* Am. Compl. ¶¶ 123–125, 127–133, 140–141, 143; (2) continued to reference the results of the Phase 2b study, *see id.* ¶¶ 134–136; (3) reported the Phase 2 open-label results and characterized the results as promising for simufilam's potential efficacy, *see id.* ¶¶ 99–101, 115, 159–165, 168, 171–175, 177; and (4) failed to connect the departures of Dr. Burns and Mr. Barbier from Cassava to misconduct alleged in ongoing government investigations, *see id.* ¶¶ 144–148. Plaintiffs broadly claim that the falsity of these challenged statements were revealed by Dr. Wang's indictment; Cassava's July 1 and August 8, 2024 Form 8-Ks; the September 26, 2024 SEC settlement; and the November 25, 2024 and March 25, 2025 Phase 3 trial results, all described above. *See, e.g.*, *id.* ¶¶ 243–44, 248, 250.

LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* Although the court must accept all well-pleaded factual allegations as true and view them in the

light most favorable to the plaintiff, it is not bound to accept as true legal conclusions couched as factual allegations. *Twombly*, 550 U.S. at 555; *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007). Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. *Iqbal*, 556 U.S. at 678.

The PSLRA imposes a separate, heightened pleading requirement in federal securities class actions, which requires that the plaintiff specify each alleged misleading statement, explain why it was misleading, and allege particularized facts giving rise to a strong inference of scienter. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 321 (2007); *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 430–31 (5th Cir. 2002). Rule 9(b) additionally requires that fraud claims be pled with particularity, a standard the Fifth Circuit interprets strictly. *Tuchman v. DSC Commc'ns Corp.*, 14 F.3d 1061, 1067 (5th Cir. 1994). This standard requires a plaintiff to specify the "who, what, when, where, and how" of the alleged fraud. *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 339 (5th Cir. 2008). Specifically, the complaint must identify the fraudulent statements, the speaker, the time and place they were made, and explain why the statements were fraudulent. *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177–78 (5th Cir. 1997).

Therefore, to state a claim under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, a plaintiff must plead six elements: (1) a material misrepresentation or omission by the defendant; (2) scienter, meaning an intent to deceive, manipulate, or defraud (or at least severe recklessness); (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation, meaning that the misrepresentation proximately caused the plaintiff's alleged injury. *See Tellabs*, 551 U.S. at 319.

ARGUMENT

Plaintiffs' Amended Complaint targets four categories of statements made by Defendants during the Class Period: statements (1) regarding government, internal, and third-party investigations; (2) referencing the historical results of Cassava's Phase 2b study of simufilam; (3) summarizing and characterizing the results of a separate, 24-month Phase 2 open-label study of simufilam; and (4) concerning the departures of Dr. Burns and Mr. Barbier from Cassava. None of the alleged misstatements states a claim.

For each category, Plaintiffs fail to plead particularized facts sufficient to establish the essential elements of a claim under Section 10(b) and Rule 10b-5, particularly when evaluated under the heightened pleading standards of the PSLRA and governing Fifth Circuit precedent. The claims fail because Plaintiffs do not adequately plead (1) any actionable or material misrepresentation or omission, (2) the required strong inference of scienter, or (3) loss causation for any challenged statement. The Amended Complaint must therefore be dismissed.

A. Plaintiffs Fail to Identify Any Actionable or Material Misrepresentation or Omission Made by Defendants

To adequately plead an actionable misrepresentation or omission, Plaintiffs must allege particularized facts demonstrating that the challenged statement was materially false or misleading *when made*. *See Masel v. Villareal*, 924 F.3d 734, 748 (5th Cir. 2019); *Kin-Yup Chun v. Fluor Corp.*, 2021 WL 1788626 (N.D. Tex. May 5, 2021). Mere disagreements over interpretation or corporate puffery do not suffice. *See Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 371–72 (5th Cir. 2004). Moreover, a statement is only misleading if it would have misled a "reasonable investor" reading it "fairly and in context" including "all [the] surrounding text, including hedges, disclaimers, and apparently conflicting information." *Omnicare Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175, 186-89, 191, 194 (2015). For

alleged omissions, Plaintiffs must show Defendants had a duty to disclose the omitted information. *See R2 Invs. LDC v. Phillips*, 401 F.3d 638, 644–46 (5th Cir. 2005).

1. *Plaintiffs fail to identify any misrepresentation or omission made by Defendants about the government, internal, and third-party investigations.*

The first category of alleged misstatements in the Amended Complaint concerns Defendants' public statements about government, internal, and third-party investigations. Plaintiffs target: (1) an October 12, 2023 press release responding to the CUNY Report, stating it made "no findings of data manipulation" and CUNY had "no legitimate basis" for accusations against Cassava personnel because it "did not interview any employee of Cassava," Am. Compl. ¶ 123; (2) statements in SEC filings (Nov. 7, 2023; Feb. 28, 2024; and May 10, 2024) that "[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors," *id.* ¶¶ 125, 127, 132; and (3) a February 28, 2024 press release and Annual Report stating an internal investigation by Orrick found "no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct," *id.* ¶¶ 129–130.

Plaintiffs fail to plead particularized facts showing that any of these statements were false or misleading. Indeed, Plaintiffs do not allege that: (1) the October 12, 2023 press release mischaracterized the CUNY Report; (2) CUNY had, in fact, interviewed Cassava employees; (3) any government agency had informed Cassava of evidence of research misconduct or wrongdoing by the Company or its personnel at the time the statements were made; or (4) Cassava's internal investigation by Orrick *had* uncovered evidence to substantiate claims that Cassava or its employees engaged in or were aware of research misconduct (it did not). In fact, each challenged statement was true.

First, Cassava's October 12, 2023 statement accurately characterized the CUNY Report, which the report itself confirms. The report states that the CUNY committee was "unable to objectively assess the merit of the allegations" and could not "make an objective assessment for even a single allegation" due to Dr. Wang's failure to provide underlying data. CUNY Report at 1, 7. Thus, CUNY did not make any final, adjudicated findings of misconduct; Cassava merely accurately summarized that status and noted questions about the report's authenticity. Am. Compl. ¶ 80. Further, the report details interviews only with Dr. Wang and CUNY personnel; there is no mention of interviews with Cassava employees. CUNY Report at 1, 3–4. Cassava's conclusion that CUNY therefore had "no legitimate basis" for accusations against Company employees based on that report is, at worst, a non-actionable statement of opinion regarding an admittedly inconclusive third-party document. *See Southland*, 365 F.3d at 371–72 (distinguishing between factual statements and opinions or puffery, explaining that statements are non-actionable when they are "of the vague and optimistic type that cannot support a securities fraud action . . . and contain no concrete factual or material misrepresentation"). Finally, *Science* magazine made the report *publicly available* before Cassava's statement about it through a link in its article about the report. *See supra,* fn. 4. Thus, investors were free to evaluate Cassava's brief characterization against the primary source—the report itself. *See Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 216 (5th Cir. 2004) (holding that alleged misrepresentations regarding gas prices were not materially misleading, where gas prices are publicly available).

Second, the statements in SEC filings—that "[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors," Am. Compl. ¶¶ 125, 127, 132—were factually correct reports of the communications received by the Company *at that time*. Plaintiffs plead no facts suggesting

that any government agency had, in fact, informed Cassava of any such findings before May 10, 2024 (the date of the last challenged statement).

Plaintiffs instead complain the statements were "artfully" worded to omit third parties like Dr. Wang. *See id.* ¶¶ 128, 131. But Defendants' statements were not "artful"; they specifically and clearly referenced what the government had (or had not) told them about Cassava's own officers, employees, and directors. Plaintiffs make no allegation that the government had told Cassava anything about any wrongdoing by Dr. Wang or any other third party. *See Ind. Elec. Workers' Pension Tr. Fund IBEW v. Shaw Grp., Inc.*, 537 F.3d 527, 541 (5th Cir. 2008) (stating that for an omission to be actionable it must "affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists"); *see also Gambrill v. CS Disco, Inc.*, 2025 WL 388828, at *6 (W.D. Tex. Jan. 30, 2025) (Ezra, J.). Defendants had no duty to disclose more than what they accurately stated regarding information received about the Company and its personnel. *See R2 Invs.*, 401 F.3d at 643–44 (finding no duty to disclose internal analyses or speculate on future outcomes where statements made were accurate). Reporting accurately on what has (and has not) been communicated is not fraud. Plaintiffs' contrary theory would impose a duty the securities laws do not recognize; to opine on the status of non-Company actors in the middle of confidential agency inquiries.

Third, the February 28, 2024 statement that an internal investigation by Orrick found "no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct," Am. Compl. ¶¶ 129–130, accurately reported the findings of that investigation. Plaintiffs plead no facts suggesting this statement misrepresented Orrick's actual findings or conclusions about the Company and its employees. Again, Plaintiffs complain the statement omits third parties, *id.* ¶ 131, but Plaintiffs have not alleged that Orrick's investigation

found any wrongdoing by such third parties, let alone that the scope of the investigation even included third parties like Dr. Wang. It's not parsing. A company may accurately disclose the results of its internal investigation focused on its own personnel without speculating about the actions of its vendors. *See R2 Invs.*, 401 F.3d at 643–44.

2. *Plaintiffs fail to plead that statements referencing historical Phase 2b results were material misrepresentations.*

Plaintiffs next challenge Defendants' references in a March 2024 presentation by Dr. Burns and Cassava's May 10, 2024 Form 10-Q to the positive results originally reported from the Phase 2b study in 2020. Am. Compl. ¶¶ 132–36. Plaintiffs allege that these summaries were misleading because Defendants knew the data was unreliable. *Id.* ¶¶ 134–136. This claim fails to identify an actionable misrepresentation for several reasons.

First, the statements accurately recounted clinical results that had already been reported years earlier. *Id*. Plaintiffs do not allege these summaries inaccurately described what the Company *had originally claimed*. And accurately summarizing historical results is not misleading. *See Nathenson v. Zonagen Inc.*, 267 F.3d 400, 419–20 (5th Cir. 2001); *see also Kapps*, 379 F.3d at 211–12; *McCloskey v. Match Grp., Inc.*, 2018 WL 4053362, at *4 (N.D. Tex. Aug. 24, 2018) ("Courts have consistently rejected attempts by plaintiffs to plead falsity based on accurate reports of historical performance.").

Second, information already disseminated cannot form the basis of a fraud claim. *See Kapps*, 379 F.3d at 213–14 & n.7 (emphasizing the importance of the "total mix" of information available to the market). By early 2024, the market was saturated with information challenging the Phase 2b study. For example, an August 2021 Citizen Petition (and three supplements) called the Phase 2b results into question and raised concerns about Dr. Wang's performing the Phase 2b re-analysis. Contemporaneous press reports suggested that the SEC and DOJ were investigating

Cassava based on these same concerns. *See* Am. Compl. ¶¶ 66–69, 74–76. Indeed, these precise allegations formed the basis of a number of claims in the Consolidated Action. *See* Consolidated Action, Dkt. 68. Given this extensive public discourse, brief, accurate summaries of the results originally reported nearly four years prior were not misleading; reasonable investors could evaluate them in light of the known controversies. *See Greenberg v. Crossroads Sys., Inc.*, 364 F.3d 657, 670–72 (5th Cir. 2004); *Kapps,* 379 F.3d at 213–14 n.7.

3. *Plaintiffs fail to identify any misrepresentations Defendants made about the Phase 2 open-label results.*

Plaintiffs next challenge statements made between February 7, 2024, and October 8, 2024—including descriptions in press releases, SEC filings (such as the 2023 Form 10-K and subsequent Form 10-Qs), open letters, and executive commentary—characterizing results from the 24-month Phase 2 open-label study. Plaintiffs target statements about "No Decline in Cognition Scores" for certain patients completing the study, Am. Compl. ¶¶ 159, 163–164, and optimistic descriptions of those results like "stable cognition," "unlike any Alzheimer's trial ever," "remarkable," and "unheard of," *id*. ¶¶ 168, 171, 173, 175. Plaintiffs allege these were misleading primarily because they omitted details about the methodology of the study and were overly positive. *Id.* ¶¶ 29, 102–114, 165. These statements are not actionable for several reasons.

First, the core factual statements that Defendants made about the Phase 2 open-label results were accurate. Specifically, (1) "[p]atients with mild Alzheimer's disease who received simufilam treatment continuously for two years" in fact "had no decline in ADAS-Cog scores" as a group; (2) "[p]atients with mild Alzheimer's who received simufilam treatment non-continuously" in fact "declined 1 point on ADAS-Cog" as a group; and (3) "[p]atients with moderate Alzheimer's who received simufilam treatment continuously for two years" in fact "declined 11.05 points on ADAS-Cog" as a group. *See Id.* ¶ 160. Plaintiffs do not allege that any of these statements were false.

Reporting factually accurate results for clearly defined statistical subgroups is not fraudulent. *See Nathenson*, 267 F.3d at 420.

Second, Defendants accurately disclosed the relevant analysis sets and methodology. Plaintiffs claim that Defendants hid the study's methodology by failing to reveal that the accurate results (described above) were recorded from only a subset of the over 200 patients who initially entered the study. Am. Compl. ¶¶ 102–109, 165. This is incorrect. The February 7, 2024 press release that first disclosed the results explicitly stated that the "study enrolled *over 200 patients with mild to moderate Alzheimer's*" and that the results applied to cohorts of "n=47," "n=40," and "n=32" respectively, clearly identifying that those results were derived from a subset of the original 200 participants. *See* Ex. B [February 7 Press Release] (emphasis added).

Plaintiffs cite ICH E9 as the analysis set standard they would have preferred, but they do not allege the Defendants claimed ICH compliance for the Phase 2 open-label study or that using a different end-of-trial analysis set rendered any statement about the open-label results false. Plaintiffs' preference for a different analysis set is a non-actionable disagreement over methodology. *See Nathenson*, 267 F.3d at 419–20 ("where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study").

Third, Plaintiffs are incorrect that Cassava did not warn investors that the analysis set used in the Phase 2 open-label study may differ from the analysis set used in the later, Phase 3 study. Am. Compl. ¶ 110. Indeed, Cassava's 2023 annual report stated that because "FAS data is specific to each phase of a study, the FAS for the 24-month study *may differ from the FAS for other phases*." *See id.* ¶ 163.

Fourth, the February 7, 2024 press release's "Study Limitations" section squarely disclosed the limitations of the open-label study that Plaintiffs claim were concealed by Defendants: that

open-label design and small subgroups "may introduce clinical or statistical bias"; that "different methods of statistical analysis . . . may lead to objectively different numerical results"; that results were "top-line" and subject to change pending a final audit; and that open-label data "do not constitute . . . regulatory evidence of safety or efficacy." *See* February 7 Press Release. These disclosures defeat any omission theory and reinforce that any characterizations of the study's results were framed with the study's limitations. *See Omnicare*, 575 U.S. at 189–94 (opinion statements not actionable where basis and uncertainty are disclosed); *see also Rubinstein v. Collins*, 20 F.3d 160, 167–68 (5th Cir. 1994).

Fifth, optimistic descriptors like "remarkable," "unheard of," or "unlike any Alzheimer's trial ever" constitute non-actionable corporate puffery when applied to accurately reported data from an early-stage, open-label study. That is especially so when the same disclosures caution about bias, method sensitivity, and provisional "top-line" status. *See* Am. Compl. ¶ 175 (Mr. Barry's October 8, 2024 letter about the Phase 2 open-label results notes that the study "was not powered for, and did not reach, statistical significance" and recommends readers "review the results for yourself."). These are "generalized, optimistic statement[s]" lacking measurable specificity upon which no reasonable investor would rely as guarantees. *See Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 869 (5th Cir. 2003); *Southland*, 365 F.3d at 372.

Finally, Defendants had no duty to speculatively compare the Phase 2 results' predictive value to potential Phase 3 outcomes when reporting the Phase 2 data. Companies are not required to preface accurate reports of current data with speculative analyses of future trial designs. *See R2 Invs.*, 401 F.3d at 643–44. The inherent differences and risks between study phases are well understood, *see, e.g., Nathenson,* 267 F.3d at 404 (acknowledging the well-understood differences

between clinical trial phases), and were, in any event, disclosed by Defendants along with the Phase 2 open-label results, *see supra*.

4. *Plaintiffs fail to plead that statements about executive departures from Cassava were false or misleading.*

Lastly, Plaintiffs challenge statements in the July 17, 2024 Form 8-K concerning the departures of Barbier and Burns, alleging they misleadingly omitted the connection to the ongoing investigations. *See* Am. Compl. ¶¶ 145, 147–148. This claim fails because the statements were true, and Defendants had no duty to disclose internal reasons for the changes at that time.

The statements about Barbier's resignation—describing it as "Other Than for Cause" and "not a result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices"—accurately reflected the contractual characterization and the standard disclosure language used to comply with Item 5.02(a)(2) of Form 8-K. *Id*. ¶ 145. Plaintiffs plead no facts showing these characterizations were untrue under Barbier's agreement or that a reportable disagreement occurred. Nor did the securities laws require Defendants to disclose internal reasons for the personnel changes; companies must only disclose the fact of an executive departure unless plaintiffs have "alleged facts that demonstrate that defendants had a duty provide more detail on the reason for [the executive's] departure." *See Firefighters Pension & Relief Fund of the City of New Orleans v. Bulmahn*, 147 F. Supp. 3d 493 (E.D. La. 2015), *aff'd sub nom. Neiman v. Bulmahn*, 854 F.3d 741 (5th Cir. 2017). And Plaintiffs have alleged no such facts here.

As for the accompanying aspirational statements by the new Chairman on the Company's commitment to "transparency, accountability, and highest ethical business practices," Am. Compl. ¶ 147, Plaintiffs have pleaded no facts that render those statements false. Further, those are another example of non-actionable corporate puffery lacking the measurable specificity required to be actionable. *See Rosenzweig*, 332 F.3d at 869; *Southland*, 365 F.3d at 372.

B. Plaintiffs Fail to Allege a Strong Inference That Defendants Acted with an Intent to Deceive or Severe Recklessness

Even if Plaintiffs could identify an actionable misstatement, their claims would fail for lack of scienter. To plead scienter, Plaintiffs must allege particularized facts giving rise to a "strong inference" that Defendants acted with intent to deceive or with "severe recklessness." *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 207 (5th Cir. 2009). Severe recklessness involves "highly unreasonable omissions or misrepresentations" reflecting "an extreme departure from the standards of ordinary care." *Id.* (internal citation omitted). Crucially, the inference of scienter must be "cogent and compelling," not merely "reasonable," and must be "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Allegations of motive and opportunity, without more, are insufficient to satisfy this standard. *See Rosenzweig*, 332 F.3d at 867 ("It is well established that bare allegations of motive and opportunity will not suffice to demonstrate scienter").

Plaintiffs first attempt to establish scienter by asking the Court to infer that Defendants knew that Dr. Wang had manipulated the Phase 2b study data (and therefore knew that their statements about that data and related investigations were misleading) based on two pieces of information: (1) Cassava's internal vendor audit of Dr. Wang's lab conducted in between April and September 2022, and (2) the email sent by Dr. Burns to Dr. Wang in May 2020. Neither supports the necessary inference.

First, the audit of Dr. Wang's laboratory at CUNY was a routine "Vendor Qualification" review, focused on determining Dr. Wang's suitability for *future* work; it was *not* an investigation of allegations of past misconduct against Dr. Wang. *See* Ex. A [Audit Rep.] at 5. And while the audit found procedural and quality-control issues (*e.g.*, "lack of experiment logbooks," deficient "sample management," and uncalibrated equipment), which resulted in a finding that the lab was

"unacceptable and temporarily not qualified" for *future studies*, it did *not* conclude that Dr. Wang had fabricated or falsified data *in the past*. *See id.* at 4–5, 7. Poor recordkeeping or quality control issues in 2022 do not equate to data falsification in 2020, nor do such findings render the specific statements Plaintiffs' challenge—made over a year later about entirely separate topics (*i.e.*, the CUNY draft report, government communications, and internal investigation findings about employees)—false. The audit is too remote in time and distinct in subject matter to carry the probative weight Plaintiffs demand of it.

Second, the existence of the May 2020 email and attachment from Dr. Burns to Dr. Wang does not support an inference of falsity regarding the challenged statements. While Plaintiffs allege that the email attachment contained statistical information that could have allowed Dr. Wang to partially unblind himself, Am. Compl. ¶¶ 13, 128, they crucially fail to plead any facts that plausibly establish that Defendants *knew* about this theoretical possibility *at the time* the challenged statements were made between October 2023 and May 2024. Indeed, Defendants concededly did not understand any theoretical unblinding implications *until after* the challenged statements were made. Cassava's July 1, 2024 8-K disclosure—a document upon which Plaintiffs explicitly rely—revealed that the Company learned of this possibility only when the SEC "*recently* provided the Company with new information obtained during its investigation," *i.e.*, in mid-2024. *Id.* ¶ 140 (emphasis added). Only then did Cassava determine the email attachment "could have been used" for partial unblinding. *Id.*

The securities laws do not recognize "fraud by hindsight." That is, statements cannot be retroactively rendered fraudulent by discoveries made years later unless failure to make such discoveries prior to those statements was "severe[ly] reckless[]." *Flaherty*, 565 F.3d at 207. Severe recklessness is "only present in situations where there is a danger of misleading buyers or sellers

which is either known to the defendant or is *so obvious* that the defendant must have been aware of it." *Local 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Diodes, Inc.*, 810 F.3d 951, 957 (5th Cir. 2016) (emphasis added). Here, any argument that Defendants were severely reckless for failing to understand sooner that Dr. Wang could have partially unblinded himself during the Phase 2b study fails because that discovery was *not at all obvious*. Indeed, Dr. Burns sent the email attachment to Dr. Wang, which contained complex statistical summaries of CSF biomarker data, so that Dr. Wang could evaluate the work of a separate laboratory. *See* Ex. D [SEC Compl.] ¶¶ 37–41. The SEC only determined that those statistical summaries could be reverse engineered by Dr. Wang to partially unblind himself by undertaking a sophisticated post-hoc analysis, which the agency subsequently explained to Defendants. Plaintiffs do not allege Defendants performed or should have performed a similar analysis prior to making the challenged statements. Thus, Defendants' mere possession of the email and attachment—the significance of which was not yet known and required sophisticated, hindsight analysis to uncover—cannot support an inference of severe recklessness regarding accurate statements made years later about the status of government investigations. *See Lormand v. US Unwired, Inc.,* 565 F.3d 228, 254 (5th Cir. 2009) ("fraud by hindsight" is where "there is no contemporaneous evidence at all that defendants knew earlier what they chose not to disclose until later").

Notably, the SEC itself alleged only *negligence*—not intentional fraud—regarding the email communication. SEC Compl. ¶¶ 88, 105–107. While the SEC alleged that Dr. Wang manipulated the Phase 2b results by partially unblinding himself, the SEC *did not* allege that Dr. Burns intentionally provided him with the statistics in the email attachment *so that he could do so*. *See id.* ¶ 2 ("Dr. Burns *negligently* provided information sufficient to allow Dr. Wang to partially unblind himself.") (emphasis added). If it was evident that the email attachment could be reverse

engineered by Dr. Wang to manipulate the Phase 2b data, then SEC would not have concluded that Dr. Burns was merely *negligent* in providing that attachment to Dr. Wang.

Thus, Plaintiffs fail entirely to plead particularized facts showing Defendants knew or even suspected that Dr. Wang had, in fact, manipulated the Phase 2b data or even that Defendants understood that Dr. Wang could be partially unblinded during the Phase 2b study when the statements they challenge were made. *See Shaw Grp.*, 537 F.3d at 542–43 (rejecting inference of knowledge based on access to internal data and allegations that defendants "must have known" without specific facts showing contemporaneous awareness of the falsity). Cassava's July 1, 2024 Form 8-K disclosed that Dr. Wang may have been partially unblinded and subsequent explicit warning in August 2024 *not* to rely on the Phase 2b data are not indicative of fraud or prior concealment, but rather of the Company's evolving understanding and honest attempt to update investors with material information as the Company learned of it.

Plaintiffs also fail to plead scienter regarding Defendants' statements about the Phase 2 open-label study. Accurately reporting results for a specific study group using a disclosed FAS methodology, while contemporaneously warning of study limitations and provisional "top-line" status, does not imply fraudulent intent or severe recklessness. And boilerplate allegations that executives had access to data and an obligation to ensure accuracy are insufficient under the PSLRA to plead scienter, especially when the reported clinical trial results were accurate as reported. *See Nathenson*, 267 F.3d at 420.

Finally, Plaintiffs' attempt to establish scienter with generalized allegations of motive, Am. Compl. ¶¶ 220–227, and opportunity, *id.* ¶¶ 228–234, fails under Fifth Circuit law. A universal desire to raise capital does not establish scienter. *See Owens v. Jastrow*, 789 F.3d 529, 539 (5th Cir. 2015). And such generalized allegations do not automatically impute knowledge of falsity

without particularized facts linking defendants to contemporaneous knowledge contradicting those statements, which Plaintiffs have not alleged. *See In re ArthoCare Corp. Sec. Litig.*, 726 F. Supp. 2d 696, 719–20 (W.D. Tex. 2010).

In sum, Plaintiffs offer no particularized facts suggesting Defendants intended to deceive investors or were severely reckless when making accurate statements about ongoing and evolving investigations, Phase 2 open-label study results, or executive departures from Cassava. The opposing inference—that Defendants accurately reported information based on contemporaneous understanding while navigating complex and confidential inquiries—is far more plausible than Plaintiffs' theory of deliberate deception through carefully worded, factually accurate updates.

C. Plaintiffs Fail to Plead That Any of Defendants' Statements Caused Investor Losses

To plead loss causation, Plaintiffs must allege facts plausibly showing a direct causal link between the alleged misrepresentation and their economic loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005). This requires explaining with particularity that the stock price declined when the market learned the "relevant truth" previously concealed, typically through a corrective disclosure revealing the falsity of the specific prior statement, and not for other reasons unrelated to the alleged fraud. *See Pub. Emps.' Ret. Sys. of Miss. v. Amedisys, Inc.*, 769 F.3d 313, 320–21 (5th Cir. 2014); *Lormand*, 565 F.3d at 258. Stock declines caused by unrelated news or the materialization of known risks do not establish loss causation. *See Ludlow v. BP, P.L.C.*, 800 F.3d 674, 682 (5th Cir. 2015) (stock drops tied to new adverse events do not necessarily reveal prior falsity). Plaintiffs' attempts to establish loss causation fail, as each of the "corrective" disclosures they allege did not reveal any truth Defendants allegedly concealed.

For example, Plaintiffs allege that the disclosures between June and September 2024—regarding Dr. Wang's indictment, Cassava's discovery of the potential unblinding email, the Company's warning not to rely on Phase 2b data, and the SEC settlement— were "corrective."

Am. Compl. ¶¶ 139, 142, 152, 157. But each of these disclosures revealed *new* information and developments regarding the progression and outcomes of government investigations, not that Defendants' prior status updates about government investigations were false *when made*. That is, they did not reveal any falsity in Defendants' *prior, specific, and true statements* about what the CUNY Report *actually found*, what government agencies *had told* Cassava as of early 2024, or what Orrick *had concluded* as of February 2024. Nor did they correct or even speak to the reasons for Mr. Barbier's or Dr. Burns's departures from Cassava. *See FindWhat Inv'r Grp. v. FindWhat.com*, 658 F.3d 1282, 1311 n.27 (11th Cir. 2011) (cited approvingly in *Amedisys*, 769 F.3d at 321) (corrective disclosure must reveal the falsity of the specific prior statement); *Dura*, 544 U.S. at 342–47 (loss causation requires that the revelation of the truth of the alleged misrepresentation cause the loss); *Alaska Elec. Pension Fund v. Flowserve Corp.*, 572 F.3d 221, 228–31 (5th Cir. 2009) (corrective disclosure must reveal the previously concealed truth).

Plaintiffs alleged corrective disclosures about the Phase 3 trials in November 2024 and March 2025 are similarly flawed. Am. Compl. ¶¶ 178–191. The Phase 3 trials' failure to demonstrate the efficacy of simufilam to treat Alzheimer's was completely disconnected from the alleged falsity of earlier statements about the separate Phase 2 open-label study. Indeed, the failure of a drug in pivotal Phase 3 trials is the materialization of an inherent, disclosed risk in drug development[8] and was the direct cause of the stock collapse. It does not reveal that earlier statements about Phase 2 open-label results, which accurately described different data using a different methodology and expressly cautioned that open-label results are not regulatory evidence

[8] Indeed, Cassava continuously disclosed the risk that the trials may not succeed in demonstrating simufilam's efficacy in SEC filings (such as 10-K filings) throughout simufilam's development.

and may not predict Phase 3 outcomes, were false when made. It simply demonstrates that promising early-stage results did not translate to Phase 3 success, which is a common occurrence.[9]

Thus, Plaintiffs rely on alleged corrective disclosures that did not (and could not) correct any information in the statements by Defendants that they challenge. Their theory of loss causation fails as a matter of law, and their Amended Complaint therefore must be dismissed.

CONCLUSION

Because Plaintiffs have failed, for each category of challenged statements, to plead particularized facts establishing actionable misstatements or omissions, a strong inference of scienter, or loss causation under the heightened standards of the PSLRA and governing Fifth Circuit precedent, the Amended Complaint fails to state a claim upon which relief can be granted and must be dismissed with prejudice unless consolidated into the Consolidated Action.

[9] Additionally, the market reacted positively to the February 2025 ClinicalTrials.gov posting, which revealed the full details regarding the FAS that Plaintiffs claim were fraudulently omitted from the initial disclosures of the Phase 2 open-label results. This further undermines loss causation. If the revelation of the "truth" (the specific FAS definition) caused the stock price to increase, it demonstrates that the allegedly omitted information did not cause Plaintiffs' losses.

Dated: November 6, 2025

Respectfully submitted,

/s/ *Gregg Costa*
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CERTIFICATE OF SERVICE

The undersigned certifies that on November 6, 2025, a true and correct copy of the foregoing was served upon each attorney of record through the Court's CM/ECF system.

/s/ *Gregg Costa*
Gregg Costa

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

CARLOS PÉREZ-COTAPOS UGARTE, MARIA ISABEL URETA BAZÁN, CARLOS PÉREZ-COTAPOS SUBERCASEAUX, INVERSIONES ANE MIREN LIMITADA, SHERYL GROVE, and HOORIEH ALAGHEMAND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

CASSAVA SCIENCES, INC., RICHARD JON BARRY, JAMES W. KUPIEC, REMI BARBIER, LINDSAY BURNS, and ERIC SCHOEN,

Defendants.

Case No. 1:24-CV-01525-DAE

DECLARATION OF GREGG COSTA IN SUPPORT OF DEFENDANTS CASSAVA SCIENCES INC.'S, RICHARD JON BARRY'S, JAMES W. KUPIEC'S, AND ERIC SCHOEN'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

I, Gregg Costa, declare:

1. I am an attorney at the law firm of Gibson, Dunn & Crutcher LLP, am admitted to practice in this District, and am counsel for Defendants Cassava Sciences, Inc., Richard Jon Barry, James W. Kupiec, and Eric Schoen in the above-referenced action. I submit this affidavit in connection with the above-referenced Defendants' Motion to Dismiss Plaintiffs' Amended Complaint.

2. Attached are true and correct copies of the following exhibits:

Exhibit A: Cassava's final, signed report with attachments memorializing its findings and conclusions as a result of its 2022 inspection and audit of Dr. Hoau-Yan Wang's laboratory at the City University of New York.

Exhibit B: Cassava's February 7, 2022 Press Release entitled "No Decline in Cognition Scores in Patients with Mild Alzheimer's Disease Who Received Simufilam Continuously For 24 Months."

Exhibit C: An Order by Judge Theodore D. Chuang dismissing the Department of Justice's indictment against Dr. Hoau-Yan Wang with prejudice.

Exhibit D: The Securities and Exchange Commission's September 26, 2024 Complaint against Cassava, Remi Barbier, and Dr. Lindsay Burns.

I declare under penalty of perjury that the foregoing is true and correct. Executed on November 6, 2025.

/s/ *Gregg Costa*
Gregg Costa

CASSAVA sciences

Cassava Audit Number: _A27__

Audit Report

Organization Audited:	The City College of New York (CCNY), School of Medicine Department of Molecular, Cellular, and Biomedical Sciences Center for Discovery and Innovation (CDI)
Address, Phone Number, and Website (if available):	CCNY CDI building 160 Convent Avenue New York, NY 10031
Point of Contact: *(Name, Title, and Email):*	Zhe Pei, Ph.D. Research Fellow topeizhe@hotmail.com Hoau-Yan Wang, Ph.D. Principal Investigator hoauyan@gmail.com

Audit Date(s):	Audit inquiry/document review: 11-18 Apr 2022 and 16-17 Aug 2022 On-site audit: 21-22 Sept 2022
Auditor(s):	Laura A. Rodriguez, Sr. Director of Clinical Quality Systems Michael Marsman, PharmD, SVP Regulatory Affairs
Audit Type:	☒ Vendor Qualification ☐ Study ☐ Site (Site #_____)
Protocol Number: (*If applicable*)	PTI-125-02
Project Name: (*If applicable*):	*A Phase 2b, Randomized, Double-blind, Placebo-controlled, Multiple Dose, Biomarker and Safety Study of PTI-125 in Mild-to-moderate Alzheimer's Disease Patients*

Cassava Audit Number: _A27__

Audit Report

Auditor(s):

Title	Name	Signature/Date
Sr. Director Clinical Quality Systems	Laura A. Rodriguez	DocuSigned by: Laura A. Rodriguez Signer Name: Laura A. Rodriguez Signing Reason: I am the author of this document Signing Time: 18-Oct-2023 | 14:52 CDT 593B48548E2E4CA7B2559CBECDE6911E
SVP, Regulatory Affairs	Michael Marsman, PharmD.	DocuSigned by: Michael Marsman, Pharm D Signer Name: Michael Marsman, Pharm D Signing Reason: I approve this document Signing Time: 18-Oct-2023 | 16:08 CDT 6252303FF961490FACFF567B84CF70BC

Audit Report

I. EXECUTIVE SUMMARY

An onsite vendor qualification audit of The City College of New York School of Medicine (CCNY) was performed on 21-22 September 2022 by Cassava Sciences' (Cassava) Sr. Director of Clinical Quality Systems, Laura A. Rodriguez and SVP of Regulatory Affairs, Michael Marsman PharmD. An initial vendor audit inquiry to review CCNY quality management documentation was also performed on 11-18 April and 16-17 Aug 2022 to verify if the laboratory had the necessary quality documents and practices in place in accordance with cGLP guidance relevant to the research work being conducted.

The purpose of the audit and audit inquiry was to assure Cassava that CCNY has adequate facilities, resources, processes, and a quality management system in place to perform biomarker analysis and research services for Cassava's clinical studies and to ensure the work performed complies with relevant regulations and guidance documents. Though the contract with CCNY stated the work was not subject to cGLP requirements it was expected that the facility would perform the contracted work according to sound scientific principles, many of which are also cGLP requirements, in compliance with CCNY Medical School standard operating procedures (SOPs) with review by supervisory technical staff.

The following regulatory and guidance documents, were used as references for the audit and for identifying non-conformance for observations found (***See Attachment A***):

- 21 CFR Part 11, *Electronic Records; Electronic Signatures*
- 21 CFR Part 50, *Protecting of Human Subjects*
- *21 CFR Part 58, Good Laboratory Practices for Nonclinical Laboratory Studies*
- ICH E6 R2, *Good Clinical Practice: Integrated Addendum to ICH E6 (R1)*
- *Guidelines for Human Biospecimen Storage, Tracking, Sharing and Disposal within the NIH Intramural Research Program*

II. AUDIT OVERVIEW

An initial vendor audit inquiry to review CCNY quality documentation was performed on 11-18 Apr 2022 and 16-17 Aug 2022 by email (***See Attachment B***). The questions sent were transferred to a word document by Dr. Zhe Pei (***See Attachment C***) who assisted in responding to the requested information. This document was utilized to provide responses by both CCNY and the CSI auditor. This initial inquiry was to determine if CCNY had the minimum quality documents and processes in place to support biomarker analysis and research since their contract did not require them to be cGLP compliant. During this time, obtaining the requested information was difficult due to Dr. Pei's and Dr. Wang's academic schedule. Over the course of a few months, Dr. Pei sent the following documentation for review:

- Audit Inquiry Responses
- Certificate of Analysis for many reagents
- Dr. Pei GCP Training Record

Upon review of the documentation and responses provided by Dr. Pei from April to August 2022, it was determined that a formal on-site audit was needed to fully review the CCNY School of Medicine's processes, procedures, and quality documentation that were in place as there were many deficiencies identified with the initial information provided.

Audit Report

On 19 September 2022, an impromptu on-site audit was scheduled with Dr. Hoau-Yan Wang and Dr. Zhe Pei to be conducted 21-22 Sept 2022. This was scheduled as a result this auditor's preliminary findings from the initial audit inquiry/document review and an FDA inspection of the laboratory on 14-16 Sept 2022. Due to the audit being scheduled so quickly, a formal agenda was not created.

The onsite audit began with an opening meeting on 21 September 2022, where the audit objectives and purpose were discussed with the CCNY Representatives. The following were present for the opening meeting:

- Dr. Hoau-Yan Wang, Principal Investigator (CCNY)
- Dr. Zhe Pei, Research Fellow (CCNY)
- Dr. Michael Marsman, SVP Regulatory Affairs (Cassava Sciences)
- Ms. Laura A. Rodriguez, Sr. Director Clinical Quality Systems (Cassava Sciences)

The audit consisted of a tour of the laboratory, interviewing Dr. Wang and Dr. Pei, and an extensive review of the laboratory's equipment calibration and maintenance records, sample management to include sample storage and tracking, sample shipping manifest forms, ELISA and Western Blot reagents certificate of analysis, personnel training records, and study records.

The close out meeting was held on 22 September 2022 to discuss the audit and any observations identified. Present for the close out meeting were the following:

- Dr. Hoau-Yan Wang, Principal Investigator (CCNY)
- Dr. Zhe Pei, Research Fellow (CCNY)
- Dr. Michael Marsman, SVP Regulatory Affairs (Cassava Sciences)
- Ms. Laura A. Rodriguez, Sr. Director Clinical Quality Systems (Cassava Sciences)

The audit resulted in **5** critical observations **2** major observation, **1** minor observations, and **0** comments. The observations and comments are documented at the end of the report in **Attachment A: *Audit Observation Report***.

Observations noted during the audit are categorized based on risks the observations may have to the study. Observations are classified into four categories: critical, major, minor, and comments.

- Critical: Observed conditions, practices, or processes that adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data. Critical findings could be a combination of major deficiencies which indicate a serious systemic failure. Critical deficiencies require immediate action.
- Major deficiency: Observed conditions, practices or processes that might adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of cGLP principles.
- Minor deficiency: Observed conditions, practices or processes that would not be expected to adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data.
- Comments: A suggestion (not a cGLP deficiency) for possible improvement to a current process, procedure, operation, and/or quality system.

All the observations were reviewed with the CCNY representatives. Recommended corrective actions were discussed at the time of the meeting as well in a follow up email sent on 28

Audit Report

September 2022. This email highlighted those corrective actions that needed to be addressed immediately (***See Attachment D***)

III. CONCLUSION:

Vendor qualification is determined based on the audit results and overall cGLP compliance. One of the following ratings is then assigned to the vendor depending on the results found:

- Acceptable Rating: Vendor meets a standard of general compliance to cGLPs that may include some major and minor observations.
- Marginal Rating: Vendor meets a standard of marginal compliance to cGLPs and/or determination of deterioration in compliance was found based on the major and/or minor observations noted.
- Unacceptable Rating: Vendor has a deficient standard of compliance with cGLPs and/or a determination of absence of controls/systems was found based on the critical, major, and/or minor observations noted. Facility warrants serious quality or compliance concerns.

Based on the lack of procedures, proper documentation practices, equipment and freezer qualification, and software access control, CCNY School of Medicine was found to not have all the required processes in place at this time to support the biomarker analysis and research services in a cGLP complaint setting. Again, though cGLP compliance was not required as part of their contract, the work was to be performed according to sound scientific principles in compliance with their SOPs which they lacked. The biggest concern for this auditor was also the lack of proper documentation practices. As a result, CCNY is considered **unacceptable** and **temporarily not qualified** to provide biomarker analysis and research services for any future Cassava studies. A temporary not qualified rating was issued as the laboratory began correcting many of observations noted during the audit. However, until all are in place and a follow-up audit is conducted to confirm the observations have been closed out, they should not be contracted for any further biomarker analysis and research work.

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IV. AUDIT DETAILS

1.0 Organizational Overview and Facilities

Dr. Wang operates independently within the school when it comes to research projects with Dr. Pei and an assistant helping him. There is no formal organizational structure as this is an educational institution. However, Dr. Pei did create an organizational chart that listed the internal laboratory structure (***See Attachment C*** - question 5).

Security to the building is tight with entrance only being allowed by being buzzed in by armed security officers where one passes through metal detectors. To continue to enter the building, one must show proof of Covid vaccination, wear a mask, and be escorted at all times.

The laboratory is located on the second floor of the building and is equipped with key card access. The freezers and refrigerators are located in the hallway outside of the laboratory areas and are locked. The laboratory area was found to be very congested and not very organized. There were many reagents that were expired within the laboratory. Pipets were stored on a pipet rack; however, there were some sitting on the bench. The weighing room where the balances were located was clean but also very congested.

2.0 Regulatory Inspection History:

CCNY recently went through an FDA inspection on 14-16 Sept 2022 where a 483 was issued. Response to the 483 was pending at the time of the audit.

3.0 Standard Operating Procedures:

The auditor noted there wasn't an SOP index nor enough SOPs in place for the work that was being conducted within the laboratory with the exception of the following:

- Pipet Calibration,
- CSF Sample Handling
- Determination of albumin in CSF and plasma for BBB integrity
- Determination of IgG in CSF and plasma for BBB integrity

These four SOPs were not well written, in a formal template, or contained an approval signature. A recommendation was provided to create one for each operation they performed within the laboratory utilizing a formal template and having an approval signature.

4.0 Equipment Records:

Equipment calibration and maintenance records were either out of date or did not exist with the exception of the pipets and balances which had current calibration certificates at the time of the audit. Essential equipment such as the FilterMax F5 (ELISA) and -80℃ freezer monitor had not been calibrated in several years. Upon further inquiry, the auditors learned that the instrument and freezer had not been validated/qualified prior to sample analysis and sample storage.

During the audit, Dr. Pei indicated the FDA had asked to see the freezer log, but she was not able to access it and told them she did not think one existed. This auditor was able to find the freezer log and confirm there is one in place that dated back from the day the freezer was installed. The

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auditor also confirmed there had been no freezer excursions at the time the PTI-125-02 and PTI-125-04 study samples were stored at the CCNY laboratory.

5.0 Training Records:

Training certificates for the three department staff were provided and found to be in order with regards to the training required for working on clinical trials. Though a formal training report was not provided, the auditor was shown a training record through the University portal for Dr. Pei.

6.0 Information Technology:

While inquiring about audit trails and history of the ELISA software and freezer, the auditor was informed that the ELISA computer being utilized was not the original computer as the previous one had been stolen. Due to this, there was no password protection to the system and/or the FilterMax F5 software though a request to update the system to provide access control had been requested through the university IT department for over a year. During the FDA inspection, the inspectors noted there was not an audit trail for the PTI-125-02 sample analysis and the system lacked one; however, this auditor was able to locate the audit trail and confirm there is one present for the PTI-125-02 sample analysis.

7.0 Study Records:

In reviewing the sample inventory, tracking, and chain of custody for PTI-125-02, the auditor noted there was no formal process and all samples for every Cassava study were grouped into one spreadsheet. Sample manifest forms were also bound together in one binder. The auditor recommended the separation of the samples within the inventory log and place each study manifest into separate binders.

Also noted was there was no formal log book entry of the experiments performed to include the pipets IDs used with calibration due dates, lot numbers and expiry dates for reagents used, when samples were received and returned, lot numbers for the ELISA and Western blot kits used, and preparation of calibration curves and/or QCs (noted later there were no QCs utilized).When discussed with the CCNY representatives, The auditor was provided with some information on what reagent and kits were used including lot numbers but there was no organization of this information. A recommendation was made to create study folders within their server with subfolders for each element to store the CoAs, calibration and maintenance certificates, and create an excel log to document the information they have with regards to lot numbers and expiry dates. Also suggested was to institute paper or electronic logbooks for all experiments going forward to include keeping a separate logbook for each study or project.

8.0 Audit Summary

CCNY School of Medicine Laboratory was found to not have all the required processes in place at this time to support the biomarker analysis and research services. They lack standard operating procedures, proper good documentation practices, and laboratory practices (i.e., equipment calibration and sample management) that are deemed critical for conducting any type of analysis to support a clinical trial. They are considered **unacceptable** and **temporarily not qualified** to provide biomarker analysis and research services for any future Cassava studies.

Audit Report

ATTACHMENT(S)

- Attachment A: Audit Observation Report.
- Attachment B: CSI Audit Inquiry Email
- Attachment C: CCNY_CSI Response to Audit Inquiry
- Attachment D: Audit Corrective Actions Email

CASSAVA sciences

Attachment A
Audit Observation Report

Observation #	Records Reviewed	Category	Observation	Non-compliance	Severity	CAPA Required	Recommendation(s) / Comment(s)
1	SOPs	Deficient Process or Procedure	The laboratory did not have any formal SOPs in place. The four SOPs provided were not well written, did not contain an approval signature, and were not in a formal template.	Lack of process and procedures in place for the work being performed.	Critical	Yes	Create SOPs in a formal template with an approval signature for all the work being performed in the laboratory. This includes sample management and good documenation practices.
2	Study Records	Deficient Process or Procedure	Lack of experiment logbooks/notebooks for all study/research work being performed.	Good documenation practices.	Critical	Yes	Institute logbooks for all experiments (suggest one for ELISA and Western Blot). Keep a separate logbook for each study you are working on. The logbooks will need to document the following information for each experiment ensuring at the end the pages are signed and dated: a.Name of Person(s) performing the experiment b.Date c.Study number d.Experiment Name e.Lot numbers of all chemicals and materials used along with the name of the item f.List of samples or reference to the file that list the sample being tested g.Documentation of experiment performed
3	Study Records	Deficient Process or Procedure	Lack of study record organization which makes it difficult to recreate what was used during sample analysis (i.e., reagents, ELISA and Western Blot kit lots, pipets, -80C freezer, and balances). All documents provided were either on a network drive, in a binder, or loose in a folder.	Good documenation practices.	Critical	Yes	Recommend creating specific folders on your network drive. These folders include the following information: a.Chemicals and Materials i.COA ii.SDS iii.Spec Sheets b.Correspondence_Emails (if study related) c.Equipment i.Balance 1.Calibration 2.Verification checks ii.-80 Freezer 1.Calibration 2.Freezer logs iii.Multimode Detector 1.Calibration iv.Pipets 1.Calibration 2.Verification checks d.Samples List_Manifest (if study related) For all Cassava Science related work, we are requesting you create a higher-level folder for each study that contains this information.
4	Equipment Records	Deficient Process or Procedure	Essential equipment such as the FilterMax F5 (ELISA) and -80°C freezer monitor had not been calibrated in several years due to Covid.	Calibration and maintenance of critical laboratory equipment.	Critical	Yes	Recommend contracting an outside vendor to immediately calibrate and service the FilterMax F5 and -80C freezer monitor.
5	Equipment Records	Deficient Process or Procedure	The -80°C freezer had not been qualified/validated prior to sample storage of study samples.	Failure to perform IQ/OQ/PQ of critical laboratory equipment.	Critical	Yes	Recommend contracting an outside vendor to immediately qualify the -80C freezer.
6	Software - access control	Deficient Process or Procedure	The ELISA computer being utilized was not the original computer as the previous one had been stolen. Due to this, there was no password protection to the system and/or the FilterMax F5 software.	IT Security	Major	Yes	Establish user login and password for the computer and for accessing the FilterMax F5 software.
7	Study Records	Deficient Process or Procedure	There was no formal process for sample inventory, tracking, and chain of custody for PTI-125-02 samples. All three studies had their samples grouped into one inventory spreadsheet. Sample manifest forms were also bound together in one binder.	Proper sample management	Major	Yes	Recommend the separation of the samples within the inventory log per study by creating separate tabs/spreadsheet for each study and placing each study's manifest into separate binders.
8	Facilities	Deficient Process or Procedure	The laboratory was very congested and not very organized. There were many reagents that were expired within the laboratory. Some pipets were sitting on the bench. The weighing room where the balances were located was clean but also very congested.	Possiblity of cross contamination and use of expire reagents.	Minor	No	Having a cluttered laboratory and pipets sitting on benches presents itself as being unclean and increases the risk of cross contamination. Recommend cleaning the labratory up and staging pipets in their rack. Though documentation that was finally received regarding the reagent and kit lots used for the study analysis demonstrated expired reagents were not used, having expired reagents within a laboratory increases the risk of their use. Recommend seperating these into a non-GLP section to avoid use during study sample analysis.

Attachment B: CSI Audit Inquiry Email

From: Laura Rodriguez
To: Zhe Pei
Subject: RE: Audit information
Date: Monday, April 11, 2022 1:26:00 PM
Attachments: image001.png

Hi Zhe,

I am available Friday, April 15th from 9-10:30 am and 1-4 pm central time. After that, I won't be available again until the week of April 25th as I am out of town next week performing an audit. In the meantime, here is a list of some of the documents that would be requested for review:

- Current Index that list the SOPs/Work Instructions/ Guides/Plans for your laboratory, so we know what is currently in place
- Business continuity and disaster recovery plan
- Regulatory agency and/or accrediting body inspection summaries for ~past 5 years
- Current certificates of accreditation
- Organizational chart for the lab
- Listing of computerized systems to include validation status
- Data review flow chart (if not in an SOP)
- COA for reagents and antibody kits being used to include expiration date and retesting if performed
- Calibration and maintenance documentation for all equipment used for AD biomarker analysis
- Equipment files relative to refrigerator and freezers for sample and reagent storage to include temperature mapping and control
- Backup generator maintenance records
- Training records for the staff involved in the validation of the method and sample analysis
- Validation documentation for software used for AD biomarker analysis and data handling (ensuring part 11 compliance as well)
- Validation of AD biomarker method (p-Tau181 and any other biomarker have been analyzed for our studies)
- Validation documentation for all equipment used for AD biomarker analysis to include balances and pipets used for any reagent preparation

Please feel free to reach out to me if you have any questions prior to us meeting.

Thank you,

Laura

Laura A. Rodriguez
Director, Clinical Quality Systems
Cassava Sciences, Inc.
7801 N. Capital of TX HWY
Suite 260

Austin, TX 78731
Office: 512-501-3179 / Mobile: 765-505-0301
lrodriguez@cassavasciences.com

From: Zhe Pei <topeizhe@hotmail.com>
Sent: Monday, April 11, 2022 1:05 PM
To: Laura Rodriguez <lrodriguez@cassavasciences.com>; Lindsay Burns <lburns@cassavasciences.com>
Subject: Re: Audit information

Hi Laura,

Thanks for the e-introduction from Lindsay!
I am currently working with Prof. Wang in CUNY, New York. May I ask if I could book an appointment with you to go through the auditing procedure & documentary works through the phone? I just want to start asap in order to be prepared.

Thank you!

Zhe

From: Lindsay Burns <lburns@cassavasciences.com>
Sent: Monday, April 11, 2022 12:58 PM
To: Laura Rodriguez <lrodriguez@cassavasciences.com>; Zhe Pei <topeizhe@hotmail.com>
Subject: RE: Audit information

Hi Laura,

I'm copying Zhe here so you can connect. Thanks!

Lindsay

From: Laura Rodriguez <lrodriguez@cassavasciences.com>
Sent: Monday, April 11, 2022 12:57 PM

To: Lindsay Burns <lburns@cassavasciences.com>
Subject: Audit information

Hi Lindsay,

Please send me the contact information for Zhe so I can start communicating with her.

Thank you,

Laura

Laura A. Rodriguez
Director, Clinical Quality Systems
Cassava Sciences, Inc.
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Suite 260
Austin, TX 78731
Office: 512-501-3179 / Mobile: 765-505-0301
lrodriguez@cassavasciences.com

1. Current Index that list the SOPs/Work Instructions/ Guides/Plans for your laboratory, so we know what is currently in place

Zhe Response: Standard Operating Procedures (SOPs) for Labs: lab safety regulatory (Please see the university lab safety requirements)

CSI Response: We need your procedures that tell the following:

- Protocol of how you conduct all laboratory processes
  - To include running or preparing calibration
  - Data processing
- Lab safety protocols

2. Disaster recovery plan

Zhe Response: Do you mean the contact information of all lab members?

CSI Response: This document tells how the university or building responds to a loss of power, natural disaster, loss of network server, etc.

3. Regulatory agency and/or accrediting body inspection summaries for ~past 5 years

Zhe Response: Couldn't find any lab regulation form, may need the template to create one

CSI Response: In speaking with Zhe, per her knowledge they have never been audited.

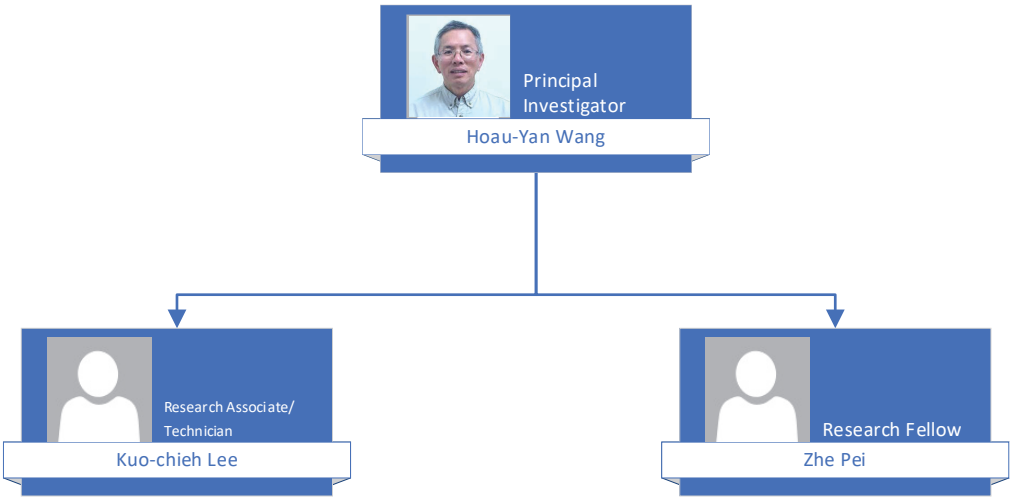
4. Current certificates of accreditation

Zhe Response: Not a GCL certificate lab.

CSI Response: Dr. Wang lab is a research lab thus does not have an accreditation from CLIA or CAP lab, so not applicable.

5. Organizational chart for the lab

Zhe Response: Zhe provided chart below.



CSI Response: Please ensure this is formalized with a revision date.

6. Listing of computerized systems to include validation status

Zhe Response: No Lab LAN available. Would you please let me know which part of the CS we need to record?

CSI Response: Instrument software

7. Data review flow chart (if not in an SOP) :

Zhe Response: N/A, because all results were forward to statisticians for further processes; we did not analyze data in this lab.

8. Certificate of Analysis (COA) for reagents and antibody kits being used to include expiration date and retesting if performed

Zhe Response: COA forms have been downloaded/requested from vendors.

CSI Response: Acknowledge receipt of documents you sent but you need to file them within your lab/network drive

9. Calibration and maintenance documentation for all equipment used for AD biomarker analysis

Zhe Response: Most lab equipment's should be covered by the maintenance plan of the University. Need to request for their documentations.

CSI Response: Yes, need to have in place calibration records for all pipets, freezer temperature recorders, instruments.

10. Equipment files relative to refrigerator and freezers for sample and reagent storage to include temperature mapping and control

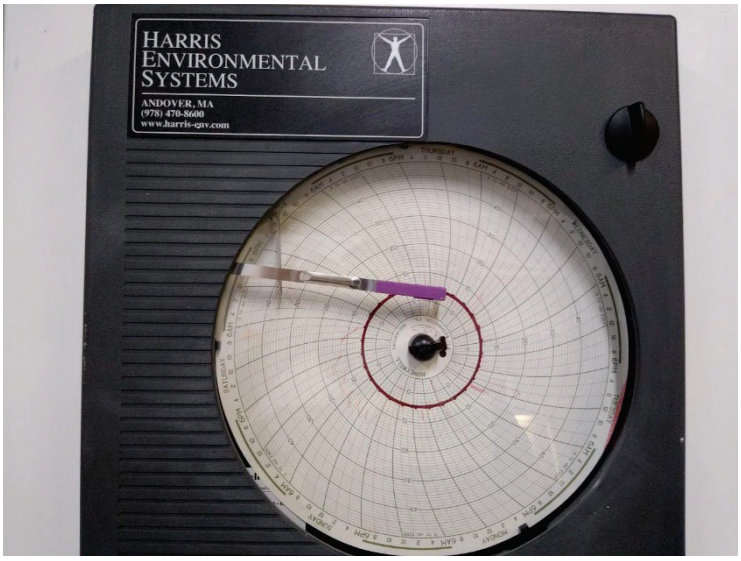
Zhe Response: Per Zhe, not sure what records are needed. Did some information for freezers.

CSI Response: You need to have the following in place and readily available for inspection:

- Need temperature Log
- Need Calibration record
- Tag freezers with calibration date

Zhe Response: The cold room temperature mapping:

CSI Response: Need to change out the charts and archive them for confirmation of no temperature excursions



Zhe Response: The -80C freezer only has temperature alert/monitor but don't have a record. May need to get extra sensors to make the record.

CSI Response: Please see if the alert/monitor is storing data any where and if it can be retrieved.

11. Backup generator maintenance records

Zhe Response: All -80°C freezers are connected to the Backup Power for the Laboratory of the building. Need to contact the maintenance department to get their maintenance records.

CSI Response: Yes, need to get maintenance records and records of testing of generator.

12. Training records for the staff involved in the validation of the method and sample analysis

Zhe Response: Per Zhe, does not have copy of these.

CSI Response: Have University HR print out your, Dr. Wang, and Kuo-Chieh Lee's taining record.

13. Validation documentation for software used for AD biomarker analysis and data handling (ensuring part 11 compliance as well)

Zhe Response: Per Zhe, they do not have any software operating instrumentation for biomarker analysis.

CSI Response: Okay for instrumentation as it does not apply. However, still need validation on statistical software used for analysis.

14. Validation of AD biomarker method (p-Tau181 and any other biomarker have been analyzed for our studies)

Zhe Response: Per Zhe, they do not have this as it is an out-of-the box kit that they use.

CSI Response: Then please have available the following information from vendors:

- Technical data sheet
- Manual of Elisa Kit you are using and antibody

15. Validation or qualification documentation for all equipment used for AD biomarker analysis to include balances and pipets used for any reagent preparation

Zhe Response: Per Zhe, they do not have this information but have calibration records.

CSI Response: Then please have available the following records:

- Calibration records for pipets
- Calibration record for balances (if used)

Attachment D: Audit Corrective Actions Email

Laura Rodriguez

From: Laura Rodriguez
Sent: Wednesday, September 28, 2022 7:30 AM
To: Hoau-Yan wang; Zhe Pei
Cc: Michael Marsman; jennifer.beidel@saul.com; Guy D. Singer (gsinger@orrick.com)
Subject: Corrective Actions from my Audit
Attachments: CUNY CDI SOP Template.docx

Good afternoon,

Thank you both for all your help last week and yesterday. As discussed last week as part of my audit, I am recommending/requesting the following immediate corrective actions be put into place:

1. Institute logbooks for all experiments (suggest one for ELISA and Western Blot). Keep a separate logbook for each study you are working on. The logbooks will need to document the following information for each experiment:
    a. Name of Person(s) performing the experiment
    b. Date
    c. Study number
    d. Experiment Name
    e. Lot numbers of all chemicals and materials used along with the name of the item
    f. List of samples or reference to the file that list the sample being tested
    g. Documentation of experiment performed

    Upon filling/completing a page, sign and date the page at the bottom. If the experiment goes to a next page add "continued from page #".

2. SOPs are going to be formalized in a template. I have created one you can use or use it as a reference for a shorter / different one.

3. Create specific folders on your network drive. These folders include the following information:
    a. Chemicals and Materials
        i. COA
        ii. SDS
        iii. Spec Sheets
    b. Correspondence_Emails (if study related)
    c. Equipment
        i. Balance
            1. Calibration
            2. Verification checks
        ii. -80 Freezer
            1. Calibration
            2. Freezer logs
        iii. Multimode Detector
            1. Calibration
        iv. Pipets
            1. Calibration
            2. Verification checks
    d. Samples List_Manifest (if study related)

For all Cassava Science related work, we are going to request you create a higher-level folder for each study that contains this information.

We can expand on this further, but this is what I am proposing as an immediate corrective action to get you in compliance with Good Laboratory Practices and Good Documentation Practices standards. I will write everything up in a formal vendor audit report to you but in the meantime, please start working on implementing these corrective actions.

Please reach out if you have any questions.

Thank you,

Laura

Laura A. Rodriguez
Director, Clinical Quality Systems
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Building 1
Austin, TX 78731
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lrodriguez@cassavasciences.com

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Envelope Originator:
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7801 N Capital of Texas highwaySuite 260
Austin, TX 78731
lrodriguez@cassavasciences.com
IP Address: 71.41.248.226

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Michael Marsman, Pharm D mmarsman@cassavasciences.com SVP, Regulatory Affairs Cassava Sciences, Inc. Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 6252303F-F961-490F-ACFF-567B84CF70BC Using IP Address: 73.158.252.185 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 18-Oct-2023 | 14:53 Viewed: 18-Oct-2023 | 16:08 Signed: 18-Oct-2023 | 16:08
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Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

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Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	18-Oct-2023 | 14:51
Certified Delivered	Security Checked	18-Oct-2023 | 16:08
Signing Complete	Security Checked	18-Oct-2023 | 16:08
Completed	Security Checked	18-Oct-2023 | 16:08

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No Decline in Cognition Scores in Patients with Mild Alzheimer's Disease Who Received Simufilam Continuously For 24 Months

Feb 07, 2024

- **ADAS-Cog Scores Were Stable in a Group of Patients with Mild Alzheimer's Who Received Drug Candidate Simufilam Continuously, Baseline to Month 24.**
- **Mild Alzheimer's Patients Who Received Simufilam Non-Continuously Declined a Group Average of 1 Point on ADAS-Cog, Baseline to Month 24.**
- **Oral Simufilam Safe, Well-Tolerated.**

AUSTIN, Texas, Feb. 07, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company, today reported top-line results of a two-year clinical safety study of simufilam, an investigational oral drug for the proposed treatment of Alzheimer's disease dementia. The study enrolled over 200 patients with mild to moderate Alzheimer's and consisted of two open-label treatment phases and a randomized, placebo-controlled withdrawal phase. Average changes in ADAS-Cog scores, baseline to month 24, indicate the following:

- Patients with mild Alzheimer's disease who received simufilam treatment continuously for two years (n=47) had no decline in ADAS-Cog scores (± 1.51 SE) as a group.
- Patients with mild Alzheimer's who received simufilam treatment non-continuously (n=40) declined 1 point on ADAS-Cog (± 1.65 SE) as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer's, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.
- Patients with moderate Alzheimer's who received simufilam treatment continuously for two years (n=32) declined 11.05 points on ADAS-Cog (± 1.91 SE) as a group.

"We're fighting Alzheimer's disease by testing simufilam, a new type of drug that has a completely different mechanism of action from monoclonal antibody drug treatments," said Remi Barbier, President & CEO. "Stable ADAS-Cog scores over 2 years is clearly a desirable clinical outcome in Alzheimer's. Our data in mild patients may emphasize the importance of treating patients early in the disease."

This was a 24-month safety study (NCT04388254). It included a pre-specified exploratory efficacy endpoint of mean change in ADAS-Cog11 scores. The study enrolled over 200 patients with mild-to-moderate Alzheimer's disease (MMSE 16-26) who were recruited from 16 U.S. clinical sites.

The safety study was conducted in three continuous phases:

- a 12-month, open-label treatment phase, followed by
- a 6-month randomized, placebo-controlled withdrawal phase[1], followed by
- 6 additional months of open-label treatment.

Study participants received simufilam oral tablets 100 mg twice-daily in the open-label treatment phases, and simufilam or matching placebo during the randomized withdrawal phase.

All study participants who completed 12 months of open-label simufilam treatment were eligible to participate in the 6-month randomized, placebo-controlled withdrawal phase. Likewise, all study participants who completed the randomized, placebo-controlled withdrawal phase were eligible for 6 additional months of open-label treatment.

Alzheimer's is a degenerative disease of the brain. Over time, a patient's cognition progressively worsens as the disease takes its toll. The science literature suggests that patients with mild Alzheimer's decline by a group average of approximately 3 points per year on the ADAS-Cog scale. With disease progression, patients move from mild to moderate to, eventually, severe Alzheimer's disease. Cognitive decline becomes more pronounced, and presumably more difficult to treat, in advanced stages of the disease.

Patients with mild Alzheimer's disease (n=87) entered the open-label study with MMSE 21-26, with ten exceptions.[2] Patients with moderate Alzheimer's entered the open-label study with MMSE 16-20, with one patient who entered with MMSE 15.

Mild patients who received simufilam for 24 continuous months (n=47) showed an average change of 0.07 points on ADAS-Cog11 (± 1.51 SE), baseline to month 24, as a group.

Mild Alzheimer's patients who received 12 months of open-label simufilam, followed by placebo in the 6-month randomized, placebo-controlled withdrawal phase, followed by an additional 6 months of open-label simufilam (n=40), declined by an average of 1.04 points on ADAS-Cog11 (± 1.65 SE), baseline to month 24, as a group.

Mean ADAS-Cog scores at baseline were approximately balanced in the group of mild Alzheimer's patients who received drug continuously versus non-continuously (15.2 and 14.6, respectively).

Safety Data

Oral simufilam 100 mg tablets twice daily appeared safe and well tolerated in this study. There were no drug-related serious adverse events. The most common treatment-emergent adverse events (TEAEs) were Covid-19 and urinary tract infection, with 33 occurrences of each.

Efficacy Data Presentation

The pre-specified cognition endpoints were analyzed on the Full Analysis Set (FAS) by Pentara Corporation, an independent consulting firm that specializes in complex statistical analysis of clinical trial results. Suzanne Hendrix, PhD, CEO of Pentara, has over 150 peer-reviewed publications of clinical trial results and statistical approaches for clinical trials, many focusing on statistical methodology for Alzheimer's disease.

We expect to report data from the two-year clinical safety study in a science forum.

Prior Results
Top-line results of the 6-month randomized withdrawal phase (i.e., the Cognition Maintenance Study) were announced July 5, 2023. Please see: https://www.cassavasciences.com/news-releases/news-release-details/oral-simufilam-slowed-cognitive-decline-randomized-withdrawal

Top-line results of the 12-month open-label phase were announced on January 24, 2023. Please see: https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-positive-top-line-clinical-results

Study Limitations
Data results from our two-year open-label safety study, or any phase thereof, do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for simufilam in Alzheimer's disease dementia. Rigorous evidence for drug safety and efficacy is derived from one or more large, randomized, placebo-controlled studies. The open-label design and limited size of this study, and each sub-group of this study, may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. In addition, we do not know how long a washout period may be needed to remove lingering drug effects, if any, from prior treatment with open-label simufilam. Different methods of statistical analysis of clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our open-label study add complexity or limitations to the scope of data interpretation.

'Top-line data' is a summary of the clinical data prior to the completion of a full and final audit or quality-control of the clinical database. We are communicating top-line data so that stakeholders may have timely access to a summary of the open-label study findings prior to us receiving the final dataset. Final data may change from top-line data.

On-going Phase 3 Studies of Simufilam in Alzheimer's Disease
Cassava Sciences is evaluating oral simufilam for Alzheimer's disease dementia in two global Phase 3 clinical studies, both of which are fully enrolled. A total of 1,929 patients with mild-to-moderate Alzheimer's disease dementia who met study eligibility criteria were randomized into the Phase 3 program from sites in the U.S., Puerto Rico, Canada, Australia and South Korea.

The first Phase 3 trial (NCT04994483) has a 52-week treatment period; 804 Alzheimer's patients were randomized into this study. Top-line results for the 52-week Phase 3 study are expected approximately year-end 2024.

The second Phase 3 trial (NCT05026177) has a 76-week treatment period; 1,125 Alzheimer's patients were randomized into this study. Top-line results for the 76-week Phase 3 study are expected approximately mid-year 2025.

About Simufilam
Simufilam is Cassava Sciences' proprietary, small molecule (oral) drug candidate that restores the normal shape and function of altered filamin A (FLNA) protein in the brain. Cassava Sciences owns worldwide development and commercial rights to its research programs in Alzheimer's disease, and related technologies, without royalty obligations to any third party.

About Cassava Sciences, Inc.
Cassava Sciences is a clinical-stage biotechnology company based in Austin, Texas. Our mission is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. Our product candidates have not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established in humans.

For more information, please visit: https://www.CassavaSciences.com

For More Information Contact:
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ESchoen@CassavaSciences.com

Cautionary Note Regarding Forward-Looking Statements and Other Notices:
Simufilam is our investigational product candidate. It is not approved by any regulatory authority in any jurisdiction and its safety, efficacy or other desirable attributes, if any, have not been established in patients.

Drug development involves a high degree of risk, and only a small number of research and development programs result in regulatory approval and commercialization of a product. Clinical results from our prior studies may not be indicative of results of future or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: the design, scope, conduct or intended purpose of our two-year, open-label study or Phase 3 program of simufilam in patients with Alzheimer's disease; the ability of simufilam to provide patients with drug effects; the apparent ability of simufilam to favor patients with mild Alzheimer's disease; the apparent safety or tolerance of simufilam in our open-label clinical trials; our current expectations regarding

timing of clinical data for our Phase 3 studies; any expected clinical results of Phase 3 studies; the treatment of people with Alzheimer's disease dementia; the safety or efficacy of simufilam in people with Alzheimer's disease dementia; our expectation to present the clinical safety study at a science forum, comments made by our employees regarding simufilam, drug effect, and the treatment of Alzheimer's disease; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "would", "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.

Such statements are based largely on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to the ability to conduct or complete clinical studies on expected timelines, to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and subsequent reports filed with the SEC. The foregoing sets forth some, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements contained in this news release. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC's website at www.sec.gov.

This news release may also contain statistical data and drug information based on independent industry publications or other publicly available information. We have not independently verified the accuracy or completeness of the data contained in these publicly available sources of data and information. Accordingly, we make no representations as to the accuracy or completeness of such data or information. You are cautioned not to give undue weight to such data.

The content of this presentation is solely our responsibility and does not represent the views of Pentara Corporation, the National Institutes of Health or any other government agency.

[1] The 6-month randomized withdrawal phase has previously been referred to as the 'Cognition Maintenance Study', or CMS.

[2] Ten patients entered with MMSE > 26 due to prior participation in a study of simufilam (n=2) or evidence of Alzheimer's disease pathology (n=8).

Source: Cassava Sciences, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

UNITED STATES OF AMERICA **v.** **HOAU-YAN WANG,** **Defendant.**	**CRIMINAL NO: 24-0211-TDC**

ORDER GRANTING MOTION TO DISMISS INDICTMENT

Upon consideration of the United States' Unopposed Motion to Dismiss the Indictment with Prejudice, ECF No. 139, it is hereby ORDERED that the Motion is GRANTED, and the Indictment (ECF No. 1), is DISMISSED WITH PREJUDICE pursuant to Rule 48(a) of the Federal Rules of Criminal Procedure. All deadlines and court dates in the current scheduling order are hereby VACATED.

DATE: October 23, 2025

THEODORE D. CHUANG
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. CASSAVA SCIENCES, INC.; REMI BARBIER; and LINDSAY BURNS, Defendants.	Case No. 24-cv-1150 JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Securities and Exchange Commission ("SEC" or "Commission") alleges as follows:

SUMMARY

1. This case involves Defendant Cassava Sciences, Inc.'s ("Cassava") misleading statements about the results of its Phase 2b clinical trials for Cassava's drug candidate PTI-125,[1] a potential therapy for the treatment of Alzheimer's disease, and the role of Defendants Remi Barbier, Cassava's founder and former Chairman and CEO, and Dr. Lindsay Burns, Cassava's former Senior Vice President

[1] PTI-125 is also known as simufilam.

of Neuroscience, in those disclosures. The announced final Phase 2b results were misleading in five ways.

2. First, Cassava claimed that "[b]ioanalyses were conducted under blinded conditions to eliminate any possibility of bias." That statement negligently omitted material information. Dr. Hoau-Yan Wang, a professor at City University of New York ("CUNY"), ran clinical laboratory tests on Cassava's behalf for Phase 2b. Before Dr. Wang began running the bioanalyses, Dr. Burns negligently provided information sufficient to allow Dr. Wang to partially unblind himself.

3. Second, Defendants negligently did not disclose that the announced results of the bioanalyses were performed by Dr. Wang, the co-inventor of PTI-125, Cassava consultant, and member of Cassava's Scientific Advisory Board. Instead, public filings with the SEC referred to Dr. Wang's laboratory at CUNY generally as an "academic lab," which although technically correct, was incomplete and misleading. By Cassava failing to name Dr. Wang, investors were not made aware that the scientist performing the analysis had a conflict of interest due to his professional and financial ties to Cassava.

4. Third, Cassava conducted an audit of Dr. Wang's laboratory at CUNY in 2022, and Cassava and Barbier negligently did not disclose the audit report's finding that Dr. Wang's laboratory was "**unacceptable** and **temporarily not qualified** to provide biomarker analysis and research for services for any future Cassava studies." (Emphases in original).

5. Fourth, Cassava and Dr. Burns negligently failed to fully disclose Dr. Burns's removal of a large portion of patients in reported cognition data. The reported episodic memory results excluded data from 40% of patients who completed the cognition test. Cassava and Dr. Burns failed to disclose the average change in errors from baseline to day 28 for the full episodic memory data set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100mg group), which showed no similar directional improvement for either the 50 mg or 100 mg group compared with placebo. And Cassava and Dr. Burns did not disclose that Dr. Burns was unblinded when she decided which patients to exclude from the reported results.

6. Fifth, Cassava and Dr. Burns negligently failed to disclose that the spatial working memory measurement reported in the Phase 2b results as showing cognitive improvement of up to 46% was a measurement selected by Dr. Burns only after she was unblinded. Cassava and Dr. Burns also failed to disclose that other spatial working memory results, including measurements identified as "key" prior to unblinding, did not show directional improvement in patients receiving PTI-125 compared with placebo.

7. In September 2020, Cassava announced final Phase 2b results that claimed that PTI-125 taken for 28 days significantly improved every measured biomarker for Alzheimer's disease compared with subjects who took a placebo. Cassava also announced that patients who took PTI-125 showed improved cognition compared to patients who took the placebo.

8. Remi Barbier, Cassava's founder and former Chairman and CEO, participated in making Cassava's misleading statements about Phase 2b. In addition to providing information sufficient to partially unblind Dr. Wang, Dr. Burns was responsible for compiling misleading Phase 2b cognition results.

9. After Cassava reported its Phase 2b trial results, the company raised more than $260M in new funding.

JURISDICTION AND VENUE

10. The SEC brings this action pursuant to the authority established in Sections 20(b) and 20(d) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. § 77t(b) and (d)].

11. This Court has jurisdiction over this action pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)].

12. Venue is proper in this district pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)], because Cassava is headquartered within this District, and Dr. Burns and Barbier reside within this District.

13. Defendants, directly or indirectly, have made use of the means or instruments of transportation or communication in interstate commerce or of the mails in connection with the transactions, acts, practices, and courses of business alleged herein.

DEFENDANTS

14. **Cassava Sciences, Inc. ("Cassava")** is a Delaware corporation with its principal place of business in Austin, Texas. Cassava is a pharmaceutical company

with one primary drug candidate, PTI-125, a potential therapeutic for the treatment of Alzheimer's disease. Cassava's shares are registered with the Commission pursuant to Securities and Exchange Act of 1934 ("Exchange Act") Section 12(b) and are listed on the Nasdaq Capital Market under the symbol "SAVA."

15. **Remi Barbier**, age 64, is the Founder, and was Chair, and Chief Executive Officer of Cassava until July 2024. He is a resident of Austin, Texas.

16. **Dr. Lindsay Burns**, age 59, was the Senior Vice President of Neuroscience at Cassava until July 2024. She is a resident of Austin, Texas. Dr. Burns co-invented PTI-125 with Dr. Wang.

OTHER RELEVANT PARTY

17. **Dr. Hoau-Yan Wang**, age 67, is a tenured associate professor at the City University of New York's School of Medicine. Dr. Wang co-invented PTI-125 along with Dr. Burns. Dr. Wang served on Cassava's Scientific Advisory Board, and Cassava retained Dr. Wang as a paid consultant until the company terminated his consulting agreement in June 2024.

FACTS

A. Cassava's Background

18. Barbier founded the company now known as Cassava in 1998. The relationship between the company now known as Cassava and Dr. Wang dates back to the early 2000s. Dr. Wang served as a consultant to the company until June 2024.

19. Dr. Burns was Dr. Wang's main point of contact at Cassava. Dr. Burns and Dr. Wang collaborated as co-authors on multiple scientific journal articles and

grant applications throughout the time that Dr. Wang served as a consultant to the company.

20. Dr. Wang and Dr. Burns discovered the molecule PTI-125, later named simufilam, which they claim binds to altered Filamin A proteins and remediates Alzheimer's disease-related pathology.

B. Cassava's Initial PTI-125 Trials

21. Clinical trials for a new drug usually proceed through three phases before the FDA will consider a New Drug Application.

22. In 2017, the FDA cleared Cassava's Investigational New Drug application for PTI-125, which allowed Cassava to begin clinical trials of the drug in humans. That same year, Cassava completed a Phase 1 human safety trial of PTI-125.

23. In 2019, Cassava ran what it called a Phase 2a trial, consisting of 13 Alzheimer's patients who all took doses of PTI-125 for 28 days. There was no placebo group.

24. One key objective of Cassava's Phase 2a trial was to measure changes in concentration of biomarkers—substances in cerebrospinal fluid ("CSF") believed to correspond with Alzheimer's disease pathology, neuroinflammation, and neurodegeneration. To measure changes in biomarkers, CSF was collected from patients before taking the drug and again after 28 days of treatment.

25. Cassava asked Dr. Wang to analyze the CSF samples collected from the Phase 2a participants. According to Dr. Wang's results, all 13 patients showed

directional improvements in multiple biomarkers, suggesting that the drug may be causing changes in biomarker levels.

26. In public announcements and SEC filings, Cassava disclosed that Dr. Wang and his laboratory at CUNY performed the biomarker tests for Phase 2a.

C. Cassava's Phase 2b Trial

27. In 2019, Cassava designed and began its Phase 2b clinical trial. That trial ultimately included 64 patients separated into three groups—one placebo group, one group taking a 50mg dose, and another group taking a 100mg dose. Each patient in each group was to take their respective treatment for 28 days.

28. Phase 2b was to be conducted as a double-blinded clinical trial, which means neither the patient nor the tester is aware which patient received which treatment. Blinding is a standard practice in many clinical trials, in part because it helps reduce the potential impact of bias.

29. Participants in Phase 2b had CSF drawn before treatment began and again after 28 days of treatment. Pursuant to the testing protocol, Cassava directed each clinical site to send patient CSF samples to the CUNY laboratory in New York where Dr. Wang performed research to be stored before laboratory analysis. Laboratory results were to be sent directly to Dr. Burns who then was to forward them to a biostatistics company hired by Cassava to compile unblinded results.

30. Participants in Phase 2b also took a battery of cognition tests before treatment and then again after 28 days to assess any changes in cognition. Those

results were also sent first to Dr. Burns who then forwarded them to the biostatistics company to perform statistical analyses on unblinded test results.

1) Round 1 Biomarker Testing

31. Cassava initially hired a laboratory in Europe to test the Phase 2b CSF samples for nine biomarkers. However, there were two biomarkers that Cassava wanted tested that the European laboratory could not measure. Cassava asked Dr. Wang to test CSF samples for those two biomarkers. All biomarker testing by the European lab (seven tests) and Dr. Wang (two tests) (collectively, "Round 1") were completed by early May 2020. Results were sent to Dr. Burns who forwarded them to the biostatistics company.

32. On May 15, 2020, Cassava filed a Form 8-K with the Commission, attaching a press release with the headline "Top-line Results from a Phase 2b Study of PTI-125 in Alzheimer's Disease Does Not Meet Primary Endpoint."

33. None of the tests performed by the European lab showed a meaningful effect of the drug treatment arms compared with the placebo. The Phase 2b Round 1 results also did not show a drug effect consistent with Dr. Wang's Phase 2a results.

34. Dr. Burns and other Cassava employees and outside scientists expressed concern with the European laboratory's results due to unexplained data variability.

35. In its May 15, 2020, press release, Cassava declared that the "study showed high variability in levels of CSF biomarkers over 28 days" and noted that it planned to re-analyze the biomarkers with the remaining patient CSF samples.

36. After this disclosure, Cassava's stock price dropped from $7.61 a share to $1.63 a share by the end of trading that day.

2) Dr. Burns Provides Data Sufficient to Allow Dr. Wang to Partially Unblind Himself

37. On May 13, 2020, the biostatistics company sent to Dr. Burns a document summarizing the statistics for each Round 1 biomarker. The document included, among other things, statistics for the lowest (min) and highest (max) sample levels in each treatment arm and in the placebo group for Day 0 (before the trial) and Day 28 (after the trial). The document also identified the largest and smallest "change from baseline" or change in biomarker levels in each treatment arm and placebo group.

38. That same day, at Cassava's request, the biostatistics company sent Cassava the unblinding codes, which allowed Cassava to know which patients participated in each treatment group. Dr. Burns received the unblinding codes.

39. On May 14, 2020, Dr. Burns sent this document with min, max, and change from baseline data to Dr. Wang and asked him to evaluate the European laboratory's data. At the time she sent the document to Dr. Wang, Dr. Burns understood that Dr. Wang had completed the testing for two biomarkers in Round 1. She also knew that Dr. Wang had individual test results identified by patient identification code for the two biomarkers that he had tested for Round 1.

40. The document sent by Dr. Burns on May 14, 2020, had sufficient information to allow Dr. Wang to match some of the test results that he ran in Round 1 with specific reported statistics.

41. Ultimately, using the information he was provided, Dr. Wang was able to unblind himself to roughly a third of the patients in Phase 2b—eight patients in the placebo group; seven in the 50 mg group; and eight in the 100 mg group.

3) Round 2 Biomarker Testing

42. On or around June 1, 2020, Cassava directed Dr. Wang to perform a reanalysis of the Phase 2b clinical samples for the seven biomarkers tested by the European lab during Round 1 using the CSF samples remaining in his lab. Dr. Wang did not, as part of Round 2, re-run tests for the two biomarkers he analyzed in Round 1. Dr. Wang also agreed to run additional biomarker tests that had not been completed in Round 1. These combined tests constituted the Round 2 testing.

43. When Dr. Wang conducted Round 2 testing, he was partially unblinded and knew for at least some patients whether they were in the placebo group or one of the treatment arms.

44. On September 14, 2020, Cassava publicized Dr. Wang's results which showed statistically significant improvement in all biomarkers in the treatment groups as compared with the placebo group. The company issued a press release and provided an investor presentation with an accompanying slide deck, all of which were filed with the Commission under Form 8-K.

45. The September 14, 2020, press release stated, "Bioanalyses were conducted under blinded conditions to eliminate any possibility of bias. An academic lab generated final results."

4) Phase 2b Cognitive Testing

46. The Phase 2b trial included cognition testing in addition to biomarker analysis. Patients in the Phase 2b trial took the Cambridge Neuropsychological Test Automated Battery ("CANTAB"), a group of cognitive testing. The CANTAB administered in Phase 2b included four different types of tests, each measuring different neurological functions. Patients were tested prior to receiving the drug (or placebo) and again after 28 days.

47. The primary CANTAB test for Alzheimer's patients was the Paired Associates Learning Total Errors Adjusted ("PALTEA"), which measures episodic memory. Cassava's two mandatory reports, its Statistical Analysis Plan ("SAP") and Trial Protocol, said that it would report statistics for *all subjects tested* as part of its cognitive testing.

48. Dr. Burns received the PALTEA results in May 2020. The data showed no improvement in episodic memory in the drug treatment arms compared with the placebo group and they showed no meaningful improvement in patient cognition.

49. After receiving these results, Dr. Burns, who was unblinded, first removed patients with missing data and patients who did not take the drug and then engaged in what she described as a "sensitivity analysis" where she removed the highest performing patients and lowest performing patients by baseline score cutoffs

across all groups until the results appeared to show separation between the placebo group and the treatment arms.

50. Dr. Burns ultimately removed 40% of the patient population from the PALTEA analysis. The methodology or criteria of subject removal that Dr. Burns utilized is not predefined in the clinical trial protocol nor the SAP.

51. Cassava did not disclose the full results of the PALTEA, but instead reported the results of Dr. Burns' sensitivity analysis as the final results. In some disclosures, Cassava included language noting that it calculated effect sizes "after removing the most and least impaired subjects." But until a Form 8-K filed on July 1, 2024, Cassava did not inform investors in any SEC filing that the reported PALTEA excluded results from 40% of patients.

52. Phase 2b cognitive testing also included an analysis of participants' Spatial Working Memory ("SWM") as a secondary outcome. Dr. Burns relied on the test's developer to identify Key Outcome Measures, which for Spatial Working Memory were "SWM Strategy" and "SWM between errors." Neither the test creator nor Dr. Burns identified any other key SWM measurement prior to receiving unblinded results, although the total errors measure reported by Cassava is a secondary outcome measure by the test developer.

53. When the biostatistics firm provided results for the two key Spatial Working Memory measurements identified by Cassava and the test developer, neither showed a clear benefit in the treatment arms.

54. Cassava did not report results for SWM between errors or SWM strategy to investors.

55. Instead, Dr. Burns selected, and Cassava reported, another measurement after she received unblinded results—SWM total errors. This was the only SWM result that was disclosed to investors.

D. Cassava Discloses Results from Phase 2b

56. On September 14, 2020, Cassava announced the results from Phase 2b in a press release, an updated presentation, an 8-K filing with the SEC, and an investor call.

57. In its September 14, 2020, press release, Cassava announced that "Alzheimer's patients treated with 50 mg or 100 mg of [PTI-125] twice-daily for 28 days showed statistically significant ($p<0.05$) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo." Cassava claimed that "[b]ioanalyses were conducted under blinded conditions to eliminate any possibility of bias" and, without identifying Dr. Wang, said that an "academic lab generated final results."

58. Cassava also claimed that "Alzheimer's patients treated with [PTI-125] showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%)."

59. Cassava also released a presentation on September 14, 2020, titled "Final Results of a Phase 2b Study of Sumifilam in Alzheimer's Disease."

60. That presentation claimed that the biomarker results from Round 1 was "invalid data," in part because some biomarkers in the placebo group "moved in opposite directions," suggesting simultaneous improving and worsening in the same patients, and that changes in biomarkers in placebo patients were uncorrelated. The presentation claimed that changes in biomarkers from Round 2 were correlated, and therefore valid.

61. The presentation claimed that the Phase 2b was a randomized, double-blind, placebo-controlled, multicenter clinical study. Cassava also claimed that PTI-125 "appears to stabilize or improve memory," noting "37% and 23% effect sizes in episodic memory vs placebo" and "17% and 46% effect sizes in spatial working memory vs placebo."

62. While the presentation did note that "*effect sizes* vs. placebo were calculated by Hedge's g after removing the most and least impaired subjects across all groups by baseline score" (emphasis added), the presentation did not disclose that the episodic memory results were from a sensitivity analysis and not from the full population.

63. The presentation did not explain that the episodic memory results were calculated only after removing 40% of the study population. The presentation failed to disclose the average change in errors from baseline to day 28 for the full episodic memory data set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100 mg group), which did not show similar directional improvement for either the 50 mg or 100 mg group compared with placebo.

64. The September 14, 2020, presentation also did not disclose that the key spatial working memory measurements identified by Cassava and the test developer prior to unblinding showed no improvement.

65. Cassava also held an investor call on September 14, 2020, where both Barbier and Dr. Burns were presenters.

66. On that conference call, Barbier claimed that "an academic lab conducted a second and final bioanalysis of the Phase 2b data" and that "the academic lab showed what we consider to be valid, proper, and expected data." He claimed that "ourselves and our advisors and pretty much anyone we've shown all the data to have confirmed that the second bioanalysis is a valid analysis."

67. Dr. Burns presented biomarker results and the cognitive results on the September 14, 2020 conference call. In her presentation, Dr. Burns described episodic memory results as "on average the placebo patients improved by one and half errors . . . but in contrast, the 50 mg dose group improved 5.7 errors on average resulting in a 37 percent effect size compared to that change in placebo." She continued that "the patients who took 100 milligrams improved by four and a half errors which is a 23 percent effect size."

68. Dr. Burns did not disclose during the investor call that the presented results for episodic memory were based on a sensitivity analysis. Dr. Burns also did not disclose during the presentation that the "averages" she referred to were calculated only after removing 40% of the study population. She did not disclose the average change in errors from baseline to day 28 for the full episodic memory data

set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100 mg group), which did not show similar directional improvement for either the 50 mg or 100 mg group compared with placebo.

69. Dr. Burns also presented the spatial working memory results, but again did not disclose that the spatial working memory test measures identified before being unblinded did not show improvements in the treatment arms compared with placebo.

70. Dr. Burns concluded by explaining that "any one of these [cognition] tests would indicate it's moving in the direction, but because we have directional improvement in both dose groups on two different tests, it gives us a lot more confidence." She explained that having both tests show directional improvement was encouraging because "it's not just two plus two, it's more like two plus two equals ten rather than four."

71. Shortly after Cassava's September 14, 2020, announcements regarding its Round 2 Phase 2b results, the company's stock more than doubled, from $3.40 to $8.41 on September 14, 2020.

72. On November 4, 2020, Cassava filed an 8-K attaching a presentation which provided additional biomarker results from Phase 2b supposedly showing that PTI-125 improved the integrity of the blood-brain barrier. Those tests were also conducted by Dr. Wang, although Cassava did not disclose that at the time. The press release and presentation continued to claim that the testing was conducted under

blinded conditions and compiled results from all Round 2 biomarker tests conducted by Dr. Wang.

73. The presentation attached to the November 4, 2020, 8-K also included results for episodic memory, but failed to disclose that any data had been excluded from the analysis.

74. On November 9, 2020, Cassava filed its Form 10-Q Quarterly Report. That report included results from Phase 2b. The 10-Q continued to claim that Phase 2b was "double-blind" and that PTI-125 "significantly ($P<0.05$) improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease compared to a placebo group" and that "Alzheimer's patients treated with [PTI-125] showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%)." That report did not disclose that the episodic memory results excluded data from 40% of the Phase 2b participants.

75. On February 8, 2021, the Company filed a Form 8-K attaching an updated corporate presentation. The presentation summarized the biomarker results from Dr. Wang. The presentation also included the top-line results from Phase 2b cognition without disclosing that any patient data had been removed from episodic memory analysis and without disclosing that the other key spatial working memory measurements showed no improvement compared with placebo.

76. Cassava continued to include Phase 2b results in filings with the SEC, including detailed results in annual reports filed March 1, 2022, and February 28,

2023, and summaries of Phase 2b results in an annual report filed February 28, 2024, and Forms 10-Q filed April 29, 2021, August 4, 2021, November 15, 2021, May 5, 2022, August 4, 2022, November 7, 2022, May 1, 2023, August 3, 2023, November 7, 2023, and May 10, 2024. In each of those filings, Cassava claimed that the bioanalyses were conducted under blinded conditions.

77. Cassava offered and sold securities during this period, and in October 2023, Barbier and Dr. Burns received stock options from Cassava.

E. Cassava Raises Funds from Public Investors Based on Phase 2b Results

78. On November 16, 2020, Cassava filed an updated prospectus supplement to sell more than 9 million shares at $8 per share, netting Cassava around $70 million after underwriting fees. The prospectus incorporated by reference certain documents, including Form 10-Q filed November 9, 2020, Form 8-K filed September 14, 2020, and Form 8-K filed November 4, 2020.

79. In February 2021, Cassava announced that given the results of Phase 2b and prior clinical results, it planned to proceed to Phase 3.

80. Cassava subsequently filed a new shelf registration statement in February 2021 to register sales of approximately $200 million, which it executed on, netting more than $190 million after paying underwriter fees. Cassava incorporated documents into the shelf registration and subsequent prospectus, including Form 10-Q filed November 9, 2020, Form 8-K filed September 14, 2020, and Form 8-K filed November 4, 2020.

F. Publicized Concerns About Dr. Wang

81. In August 2021, two individuals filed a citizen petition with the FDA—a mechanism designed for the public to petition the FDA regarding administrative and regulatory decisions—asking the agency to perform a review of the drug and claims made by the company. Citizen petitions are public documents and, thus, Cassava was alerted to the claims contemporaneously.

82. The citizen petition included claims, that, among other things, Dr. Wang had manipulated images of tests known as western blots to various academic journals as well as, collaboratively with Cassava, to the National Institutes of Health to support grant applications.

83. Barbier and Dr. Burns were made aware of the claims raised by the citizen petition around the time it was filed.

G. Audit of Dr. Wang's Laboratory

84. Following complaints raised in the citizen petition, the FDA performed a review of Dr. Wang's laboratory at CUNY. Following the FDA's review, Cassava initiated its own audit of Dr. Wang's laboratory related to his work on the Phase 2b trial. Between April and September 2022, Cassava's Senior Director of Clinical Quality Systems reviewed documents related to the Phase 2b trial and conducted a site visit to Dr. Wang's laboratory at CUNY.

85. Cassava's audit found critical issues with the laboratory and Dr. Wang's practices, including a "lack of procedures, proper document practices, equipment and

freezer qualification, and software access control." Most notably, Cassava found a "lack of experiment logbooks/notebooks for all study/research work being performed."

86. Based on these failings, Cassava determined that Dr. Wang's laboratory at CUNY were "considered **unacceptable** and **temporarily not qualified** to provide biomarker analysis and research services for any future Cassava studies." (Emphases in original). Cassava concluded that Dr. Wang's laboratory at CUNY "should not be contracted for any further biomarker analysis and research work" until a "follow-up audit is conducted to confirm the observations have been closed out." Both Barbier and Dr. Burns were generally aware of the findings in the report. However, Cassava did not sever its relationship with Dr. Wang at that time. Nor did Cassava inform investors of Cassava's internal findings regarding Dr. Wang. It was not until June 2024 that Cassava officially ended its contractual relationship with Dr. Wang.

OVERVIEW OF SECURITIES LAW VIOLATIONS

A. Defendants Negligently Misrepresented Material Facts

87. Sections 17(a)(2) and 17(a)(3) of the Securities Act make it unlawful for any person, in the offer or sale of a security, to "obtain money or property by means of any untrue statement of material fact" or a material omission necessary to make statements made not misleading, or to "engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."

88. Defendants incorrectly claimed that Phase 2b bioanalyses were conducted under blinded conditions. Defendants negligently stated in SEC filings, press releases, presentations, and verbally that the Phase 2b bioanalyses were conducted under blinded conditions. Those statements were untrue because Dr. Wang, who performed the bioanalyses, was at least partially unblinded after receiving information from Dr. Burns in May 2020. The misstatements were material because, as even Cassava noted, "blinded conditions . . . eliminate any possibility of bias." Blinding was even more important in this instance because Dr. Wang, the co-inventor of the drug and an individual with a financial stake in its success, was the scientist performing the bioanalyses.

89. Defendants failed to disclose that Dr. Wang conducted the bioanalyses in Round 2 and Dr. Wang's laboratory was later deemed unacceptable by Cassava's internal audit. Defendants' negligent failure to name Dr. Wang or his laboratory as the parties that ran the assays deprived the investing public of the ability to consider any conflicts of interest between Dr. Wang and Cassava. It also made it considerably more difficult for investors to question whether Dr. Wang remained blinded or whether he might have manipulated results to ensure investors perceived his invention as a success. Furthermore, Defendants negligently failed to inform investors that Cassava determined pursuant to their internal audit that Dr. Wang's laboratory was unacceptable and temporarily not qualified to provide biomarker analysis and research services for any future Cassava studies.

90. Defendants misled investors by reporting cognition results that excluded 40% of subjects. Defendants negligently failed to disclose that the episodic memory results were calculated only after removing 40% of the study population until July 2024. Defendants did not disclose the average change in errors from baseline to day 28 for the full episodic memory data set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100 mg group), which the full data set did not show similar directional improvement for either the 50 mg or 100 mg group compared with placebo.

91. While one presentation filed with the SEC did note that "*effect sizes* vs. placebo were calculated by Hedge's g after removing the most and least impaired subjects across all groups by baseline score" (emphasis added), the presentation failed to disclose that episodic memory results displayed in the graph were from a sensitivity analysis, not from data from the full population.

92. Cassava and Dr. Burns selected a secondary outcome measurement to report for spatial working memory and did not report results from other key spatial working memory outcome measures. Dr. Burns worked with the CANTAB developer to select key secondary measurements for spatial working memory before she was unblinded. After those measurements did not show promising results, she decided to select a new spatial working memory measurement that showed improvements in treatment arms compared with placebo. By failing to disclose the other tests that did not show directional improvement and failing to disclose that Dr. Burns only selected

the reported measurement, Defendants negligently misrepresented the full truth of the results.

93. Misstatements about Phase 2b were material. PTI-125 is Cassava's primary asset and its only realistic potential source of revenue. The company's financial status leading up to the stock sales in November 2020 and February 2021 also show the materiality of the news about Phase 2b. Several banks advised the company that Cassava would be unable to raise sufficient capital for Phase 3 testing until announcing the Phase 2b results. Following the Phase 2b result disclosures, the company's stock price rose dramatically, enabling the company to raise hundreds of millions of dollars for its Phase 3 testing.

B. Recordkeeping and Reporting Requirements

94. Section 13(a) of the Exchange Act and Rules 13a-1, 13a-11 and 13a-13 thereunder require issuers to timely file annual, current and quarterly reports, respectively, with the Commission. Implicit in these provisions is the requirement that the information provided be accurate. Exchange Act Rule 12b-20 requires that periodic reports contain all information necessary to ensure that statements made in them are not materially misleading.

95. Cassava made its misstatements in at least 15 publicly filed annual and quarterly disclosures between September 14, 2020 and February 2024 and in multiple periodic filings. Following notice of the issues related to potential biomarker test manipulation in 2021, Cassava continued to both affirmatively include misrepresentations in its publicly filed disclosures and presentations as well as

incorporate prior misrepresentations by reference into its continued disclosures. Barbier was ultimately responsible for ensuring the accuracy of the company's filings, and he filed quarterly certifications declaring that the disclosures were accurate. Dr. Burns should have known that certain provisions of the company's filings contained misleading information.

FIRST CLAIM FOR RELIEF

(Against Cassava for Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)])

96. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

97. By reason of the conduct described above, Cassava, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly: (i) obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (ii) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser. As alleged above, Cassava's negligent actions included: stating in public filings that the Phase 2b study was conducted under "blinded conditions;" reporting that the Phase 2b study was conducted by an "academic lab" and failing to name Dr. Wang or the subsequent findings against him by Cassava's internal audit; portraying a sensitivity analysis related to the Phase 2b

episodic cognitive results as the full and final results of the clinical trial; and failing to disclose that the spatial working memory measurement reported in the Phase 2b results was a post-hoc measurement selected by Dr. Burns in place of pre-selected measurements that did not show positive outcomes.

98. While engaging in the conduct described above, Cassava acted negligently.

99. By engaging in the conduct described above, Cassava violated, and unless restrained and enjoined will continue to violate, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

SECOND CLAIM FOR RELIEF

(Against Barbier for Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)])

100. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

101. By reason of the conduct described above, Barbier, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly: (i) obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (ii) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser. As alleged above, Barbier's negligent actions

included: reporting that the Phase 2b study was conducted by an "academic lab;" failing to name Dr. Wang as the sole scientist conducting the biomarker analysis for Phase 2b; and failing to disclose that Cassava deemed Dr. Wang's laboratory unacceptable pursuant to an internal audit.

102. While engaging in the conduct described above, Barbier acted negligently.

103. By engaging in the conduct described above, Barbier violated, and unless restrained and enjoined will continue to violate, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

THIRD CLAIM FOR RELIEF

(Against Dr. Burns for Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)])

104. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

105. By reason of the conduct described above, Dr. Burns, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly: (i) obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (ii) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser. As alleged above, Dr. Burns' negligent actions

included: stating in public filings that the Phase 2b study was conducted under "blinded conditions;" portraying a sensitivity analysis related to the Phase 2b episodic cognitive results as the full and final results of the clinical trial; and failing to disclose that the spatial working memory measurement reported in the Phase 2b results was a post-hoc measurement selected by Dr. Burns in place of pre-selected measurements that did not show positive outcomes.

106. While engaging in the conduct described above, Dr. Burns acted negligently.

107. By engaging in the conduct described above, Dr. Burns violated, and unless restrained and enjoined will continue to violate, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

FOURTH CLAIM FOR RELIEF

(Against Cassava for Violating Section 13(a)(1) of the Securities Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder [15 U.S.C. § 78m(a) and 17 C.F.R. § 240.12b-20, 13a-1, 13a-11, and 13a-13])

108. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

109. Cassava violated Exchange Act Section 13(a)(1) and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder by including false and misleading information in disclosure documents filed with the Commission pursuant to the Exchange Act.

110. By engaging in the conduct described above, Cassava violated, and unless restrained and enjoined will continue to violate Exchange Act Section 13(a)(1) and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder.

PRAYER FOR RELIEF

WHEREFORE, the SEC respectfully requests that the Court enter a Final Judgment:

I.

Finding that Defendants committed the alleged violations;

II.

Permanently enjoining all Defendants, their agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, who receive actual notice of the judgment by personal service or otherwise, from violating Securities Act Section 17(a) [15 U.S.C. § 77q(a)];

III.

Permanently enjoining Cassava, its agents, servants, employees, and attorneys, and those persons in active concert or participation with any of it, who receive actual notice of the judgment by personal service or otherwise, from violating Exchange Act Section 13(a)(1) [15 U.S.C. § 78m(a)] and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 [17 C.F.R. § 240.12b-20, 13a-1, 13a-11, and 13a-13];

IV.

Ordering Defendants to pay civil penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)];

V.

Pursuant to the Court's inherent authority to fashion appropriate equitable relief in this matter, prohibiting Barbier and Burns from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)];

VI.

Retaining jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court; and

VII.

Granting such other and further relief as this Court may determine to be just and necessary.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff Securities and Exchange Commission demands that this case be tried to a jury.

Dated: Washington, D.C.
September___, 2024

Respectfully submitted,

By: _____

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